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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Bowman
Application Serial No.: 09/737,185
Filed: 12/14/2000
Confirmation No.: 9139

Appeal No. ----
Group No.: 1743
Examiner: Gakh, Yelena G.

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appeal Brief

This Appeal Brief is being transmitted in this application with respect to the Notice of Appeal filed on June 28, 2005. An earlier brief was filed, but a Notice of Non-Compliant Appeal Brief mailed October 27, 2005, required this resubmission. The Appeal Brief fee was paid with our earlier brief. Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account 501923.

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APPELLANT'S BRIEF

1. Real Party in Interest

The real party in interest in this appeal is the assignee of all rights to the disclosed invention, GBF, Inc.

2. Related Appeals and Interferences

There are no appeals or interferences that will directly affect or be directly affected by, or have a bearing on the Board's decision in this appeal.

3. Status of the Claims

Claims 1-21, 38 and 40-44 remain in the case with none of the claims being allowed or allowable. Claims 22-37 and 39 were previously cancelled without prejudice. Claims 1-21, 38, and 40-44 are subject to appeal. The Summary page of the March 29, 2005, Office Action apparently inadvertently omits mention of claim 38, but it is treated on the merits on page 3 of the action.

4. Status of the Amendments

No amendment was submitted after the Office Action mailed March 29, 2005.

5. Summary of Claimed Subject Matter

As claimed in independent claim 1 and the claims dependent thereon, the present invention provides a diagnostic specimen system for identifying and controlling biomedical or toxicology specimens and managing information associated with the specimens. Diagnostic systems test for disease and the like. Toxicology tests look for toxic substances, including illegal drugs. The system provides a diagnostic or toxicology specimen container having an electronic memory tag for remote non-contact recording and reading of data stored therein. Other claims are directed to embodiments of a method of using the diagnostic system to manage information associated with the specimens.

In embodiments, the diagnostic specimen system includes a population of biomedical specimen collection vessels, such as the vessel 1, shown in Figure 1. Attached to each of the vessels 1 is a wireless electronic memory tag 3. The tags 3 remain attached to the vessels 1 as each is transported between a vessel distribution facility (such as a vendor's warehouse), a specimen collection facility (such as a doctor's office), and a specimen testing laboratory facility (such as a laboratory), as depicted by the flowchart of Figure 4.

Also, in various embodiments, the memory tags 3 store data representing an identification code for the vessel 1, the identity of the supplier of the vessel 1, and product information about the vessel 1. The data may relate to the specimen donor and identifies the specimen contained in the vessel 1. The data may also define analytical tests to be performed on the specimen. Each vessel 1 may also include an attached label 4 imprinted with an identifying bar code 7. Figures 1 and 5 show these additional features of the system.

Claim 9 and its dependents are directed to a toxicology specimen system. Collection vessels 1 are configured to receive and contain a toxicology specimen, and wireless electronic memory tags 3 are attached to the vessels. The wireless tags 3 remain attached to the vessels 1 as they are transported. The tags 3 are for non-contact storage and retrieval of information and contain stored data including an encoded electronic signature of the donor of a toxicology specimen. Claims 10-16 detail several additional features, and claim 17 recites several of those features in combination. Claim 38 is directed to the toxicology specimen collection vessel, including a tamper-indicating seal.

Yet additional embodiments of a toxicology specimen system are claimed that include a population of collection vessels 1. Each of the collection vessels 1 is configured to receive and

contain a toxicology specimen and has a wireless electronic memory tag 3 attached for non-contact storage and retrieval of information. The memory tag 3 contains stored data including an encoded electronic signature of the donor of a toxicology specimen. The population of collection vessels includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility. Members of the population are transportable between the facilities, and the tag 3 is attached to the vessel 1 such that it remains attached to the vessel 1 as it is transported between facilities.

Claim 18 recites a method for electronically storing information on a diagnostic or toxicology specimen vessel 1 and remotely reading information from the vessel 1. The method includes providing a population of biomedical specimen vessels 1, as shown in Figure 4. Attached to each of the vessels 1 is a wireless electronic memory tag 3. The population of vessels 1 includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility. The method further includes storing data on one of the memory tags 3 at the vessel distribution facility, shipping or distributing population members with the stored data from the distribution facility to the collection facility, and reading the stored information from the electronic memory tag 3 with a non-contact electronic reader or scanner at a specimen testing laboratory facility. The memory tags 3 remain attached to the vessels during the shipping or distributing.

Claim 19 recites a method involving collecting specimens in the recited vessels and storing information about the specimen and its donor.

Claim 42 recites the population of vessels for collecting toxicology specimens, with some members of the population at the vessel distribution facility, some at a collection facility and some at a testing laboratory. Claim 43 recites a similar population of biomedical specimen collection vessels.

Claim 44 covers either type of specimen collection and details procedures involved in the specimen collection phase.

In an embodiment, the method that is depicted in the flow chart labeled Figure 4 of the application includes collecting a specimen from a donor in the specimen container at the collection facility, and storing information about the specimen, donor, and/or tests to be performed on the specimen on the memory tags 3. The method may also include collecting and

storing the electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

6. Grounds of Rejection to be Reviewed on Appeal

The following rejections are on appeal:

A. Whether Appellant and U.S. Patent No. 6,535,129 to Petrick ("Petrick") claim the same patentable invention, so that Appellant's declaration under 37 CFR 1.131 can be disregarded.

B. Whether Claims 1-21 and 40-44 are indefinite under 35 U.S.C. 112, second paragraph.

C. Whether Claims 1-4, 6-7, 9-12, 14-15, 18-19, 21, 38, 41, and 44 are anticipated by U.S. Patent No. 6,535,129 to Petrick ("Petrick") under 35 U.S.C. 102(b).

D. Whether Claims 1-2, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44 are anticipated under 35 U.S.C. 102(b) by U.S. Patent No. 5,777,303 to Berney ("Berney").

E. Whether Claims 5, 8, and 13 are unpatentable under 35 U.S.C. 103(a) in view of Petrick.

F. Whether Claims 16, 17, 20, 38, 42, and 43 are unpatentable under 35 U.S.C. 103(a) over Petrick in view of U.S. Patent No. 5,613,012 to Hoffman et al. ("Hoffman").

G. Whether Claims 2 and 10 are unpatentable under 35 U.S.C. 103(a) over Berney in view of disclosure of RD 421048 A ("RD 421048 A").

H. Whether Claims 1, 6-7, 9-10, 14-15, 18-19, and 21 are unpatentable under 35 U.S.C. 103(a) over Berney in view of U.S. Patent No. 5,135,313 to Bowman ("Bowman").

I. Whether Claims 3-4 and 11-12 are unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman, and further in view of EP 1,004,359 A2 to Stevens et al. ("Stevens").

J. Whether Claims 5 and 13 are unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman and Stevens, and further in view of U.S. Patent No. 5,314,421 to Leuenberger ("Leuenberger").

K. Whether Claim 8 is unpatentable under 35 U.S.C. 103(a) over Bowman, RD 421048 A, Stevens and Leuenberger.

L. Whether Claims 16, 20,and 38 are unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman, and further in view of U.S. Patent No. 5,948,103 to Fukuzaki ("Fukuzaki").

M. Whether Claim 17 is unpatentable under 35 U.S.C. 103(a) over Berney in view of Bowman, RD 421048 A, Stevens, Leuenberger, Fukuzaki and U.S. Patent No. 6,018,713 to Coli et al. ("Coli").

7. Arguments

A. Appellant Does Not Claim the Same Patentable Invention as Petrick and so can swear behind it.

The Patent Office accorded Appellant a filing date of December 14, 2000 for the application that is the subject of this Appeal. After several official exchanges between an examiner and Appellant, an Office Action mailed January 15, 2004, rejected claims of the application for the first time under 35 U.S.C. 102(e) over U.S. Patent 6,535,129 to Petrick, which issued March 18, 2003 on an application filed November 17, 2000. The Office Action contained no statement indicating that Appellant was claiming the same invention as Petrick, though MPEP § 2308.01[1] provides in relevant part:

> If an applicant is claiming the same invention as a patent ... the application should be rejected under 35 U.S.C. 102(e)/103. A statement should be included in the rejection that the patent cannot be overcome by an affidavit or declaration under 37 CFR 1.131 but only through interference proceedings. Note, how-ever, 35 U.S.C. 135(b) and MPEP § 2307. The applicant should also be advised that an affidavit under 37 CFR 1.608(b) or evidence and an explanation under 37 CFR 1.608(b), as appropriate, must be submitted and it should be stated, if applicable, that the patentee has been accorded the benefit of an earlier U.S. application.

In the absence of any such statements from the Examiner, Appellant submitted Rule 1.131 declarations of co-inventors Jason Bowman, Danny Charles Bowman and David Michael Lewis showing invention of the claimed subject matter antedating the filing date of Petrick to remove the reference as prior art.[2] MPEP § 2308.01 further provides in pertinent part:

> If the applicant ... files an affidavit under 37 CFR 1.131, the rejection should be ... made final. The rejection should specify what the count or counts of the interference ... would be. If the applicant still disagrees ... the rejection may be appealed to the Board of Patent Appeals and Interferences, and the question of

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[1] Manual of Patent Examining Procedure, 8th Edition, Revision 2 throughout.

[2] Appellant first responded June 15, 2004 to the Office Action mailed January 15, 2004. The Patent Office then issued a Notice of Non-Compliant Amendment July 6, 2004, to which Appellant responded July 9, 2004. Appellant later also submitted a Supplemental Response to the June 15, 2004 Office Action on July 23, 2004. The declarations swearing behind Petrick are contained in these three submissions following the June 15, 2004 Office Action.

> whether the application and the reference patent are claiming the same invention may be argued on appeal....

However, in response to Appellant's declarations, the examiner did not specify counts of an interference proceeding, cited MPEP § 715 [II.][3] and concluded, without more, that Appellant's declarations were improper because the application 'claim[ed] [a] substantially identical invention to the one *disclosed* in [Petrick].'[4] (emphasis added) The examiner found no fault in the proof that applicant antedates Petrick, relying solely on the "claiming the same patentable invention" rubric to maintain the rejection. Appellant subsequently submitted an Amendment explaining that the declarations of record were proper to remove Petrick as a prior art reference,[5] to which the Examiner responded:

> [I]n claim 7 Petrick discloses "the business form of claim 1, wherein said wireless identification *device is adhered directly to the specimen or to a container containing the specimen*". The specification discloses "medical samples", "automated facility", etc., unambiguously indicating that the invention is related to a plurality of vessels ... [I]t is conventional US patent practice to define a plurality of objects by using a single article "a" in claims. Thus, the examiner considers the reference claiming "the same patentable invention as the application", and therefore the rule of 37 CFR 1.608 should be applied in this case (see MPEP §§ 2306-2308).[6]

The Examiner's failure to comply with the MPEP and misapplication of the "same patentable invention" standard compels Appellant to file this Appeal. The Examiner errs by saying applicant and Petrick claim the same patentable invention. No counts to an interference proceeding have been specified by the Examiner, as is required by MPEP § 2308.01, so Appellant is left to speculate that that the single count would be Petrick's Claim 7.

37 CFR 1.601(n) states the general rule for determining whether an application is claiming the same patentable invention as a patent thusly:

> Invention "A" is a *separate patentable invention* with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and

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[3] Paragraphs 3 of Office Action mailed November 16, 2004.

[4] Paragraph 20 of Office Action mailed November 16, 2004 (Emphasis added).

[5] Amendment filed February 16, 2005 at page 13.

[6] Paragraph 20 of Office Action mailed March 29, 2005.

non-obvious (35 U.S.C 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

The predecessor of the Court of Appeals for the Federal Circuit held in *In re Eickmeyer*, 602 F.2d 674, 202 U.S.P.Q. 655 (CCPA 1979) that the PTO cannot deny an applicant an interference on the grounds that the applicant and a patentee are not interfering in fact and also deny the applicant the opportunity to swear behind the patent on the grounds that the applicant is claiming the same invention as the patentee. Accordingly, since an interference in fact requires a two-way analysis of the "same patentable invention" rule 1.601(n), such must also apply to the interpretation of Rule 1.131.

The Trial Section of the Interferences Division of the Board of Patent Appeals and Interferences in *Winter v. Fujita*[7] set forth a two-way analysis to determine the existence of an interference-in-fact. In the first step of the analysis, the claimed invention of Petrick is presumed to be prior art to applicant. If Appellant's claim is new and non-obvious in view of Petrick's claim, the claims describe separate patentable inventions. If not, the parties are not claiming the same patentable invention. If so, we proceed to the second step in which Appellant's claim is presumed to be prior art to Petrick's, and the reverse analysis is performed. If Petrick's claim is new and non-obvious in view of Appellant's claim, the claims describe separate patentable inventions. The claims describe the same patentable inventions only if Petrick's claimed invention anticipates or renders obvious Appellant's claimed invention *and* vice versa.[8] The analysis refers only to the parties' claims, not the remainder of the specifications.

1. Evaluation of Applicant's System claims 1-17 and 40-43.

Petrick's Claims 1 and 7 read:

> 1. A business form comprising:
>
> a first portion providing chain of custody information therein; and
>
> a second portion linking said form with at least one specimen;
>
> wherein said business form further includes a wireless identification device associated therewith that electronically provides at least an identifier in response to a query for automatically establishing the chain of custody of said specimen,

[7] 53 USPQ2d 1234, 1243 (1999), reh'g denied, 53 USPQ2d 1478 (BPAI 2000).

[8] Id.

> said wireless identification device being associated with the form such that de-associating the device from the form results in at least partial destruction of the form in a manner that is readily seen through visual inspection of the form.
>
> 7. The business form of Claim 1 wherein said wireless identification device is adhered directly to the specimen or to a container containing the specimen.

And Appellant's Claim 1 states:

> A diagnostic specimen system comprising a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

(a) Assuming Petrick is Prior to Applicant for 1.601(n) test

Assuming Petrick's claim is prior art, Appellant's claim is novel. Appellant's claim describes a population of collection vessels having members at specified locations. Petrick's claim does not disclose multiple vessels at the specified locations. Appellant's claim is therefore new in view of Petrick's claimed invention.

Nor is Appellant's diagnostic specimen system an obvious variation of Petrick's business form. Nothing in Petrick's claim teaches or suggests the vessels at various locations set forth in Appellant's claim. Thus, Appellant's claim is not an obvious variation. Appellant's claim is not even directed to the same subject matter. Petrick claims a business form; Appellant claims a system comprising a population of vessels. Therefore, Appellant is not claiming the same patentable invention as Petrick's Claim 7.

(b) Assuming Applicant is prior to Petrick for 1.601(n) test

If Appellant's claim is assumed to be prior art to Petrick's, the same result obtains. Petrick's claim requires a new business form having two portions and a particular association between the business form and the wireless identification device. Appellant's claim does not disclose or suggest a business form (much less one having two portions) or any particular

relationship between such a form and an identification device.[9] Thus, Petrick's claim is non-obvious in view of Appellant's claim and the inventions are separately patentable under the *Winter* analysis.

Even if the Board eschews *Winter* and risks violating the rule of *Eickmeyer* by applying the test as one-way only, applicant is not claiming the same invention as Petrick. Appellant's claim is new and non-obvious when Petrick's claim is presumed to be prior art.

The PTO often asserts that inventions are patentably distinct and supportive of two patents in making restriction requirements. According to MPEP Section 808.02 separate classifications is a reason for insisting on restriction of distinct inventions. Petrick is classified in U.S. Class 340/572.1, relating to electrical communications. Completely unrelated to electrical communications is U.S. Class 436/56, where applicant's published application has been classified.

2. Evaluation of Appellant's method claims 18-21, 44

Furthermore, Appellant's Claim 18 reads:

> A method for electronically storing information on a diagnostic or toxicology specimen vessel and remotely reading information from the vessel comprising:
>
> providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached thereto, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility;
>
> electronically storing data on one of the electronic memory tags at the vessel distribution facility;
>
> shipping members including the electronic memory tags attached thereto with electronically stored data from the vessel distribution facility to the specimen collection facility; and
>
> reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

[9] This is so although Appellant's claim is broad enough to be infringed by a device having the features described by Petrick's claim. While some embodiments of Petrick could be implemented to infringe Claim 1, and *vice versa*, such infringements are not inevitable. If a practitioner of Appellant's Claim 1 does not use a business form, Petrick is not infringed. If a practitioner of Petrick does not have containers at the locations of Appellant's Claim 1, Appellant's Claim 1 is not infringed.

The Examiner apparently asserts that Appellant's Claim 18 and Petrick's Claim 7 claim the same patentable invention, although Appellant's claim describes a method of storing information, and says nothing about the business form that is Petrick's invention. Furthermore, Appellant's method includes storing data on its tags at a vessel distribution facility, while Petrick's claim says nothing about such a facility. Applicant's method claims have no disclosure or suggestion of a two-part business form as claimed by Petrick. Therefore, Appellant's Claim 18 is not claiming the same patentable invention as Petrick's Claim 7.

The Examiner insists that Appellant and Petrick claim the same patentable invention without specifying what the count or counts of an interference would be, as is required under 37 CFR 1.131. No doubt the Examiner has not done so because the task is impossible: Appellant is not claiming the same patentable invention as Petrick. Therefore, Appellant can properly swear behind Petrick, and the rejections of Appellant's application using Petrick as prior art should be reversed.

B. The Scope of Claims 1-21 and 40-44 is Definite under 35 U.S.C. 112, Second Paragraph.

The Examiner rejected Claims 1-21 and 40-44 as indefinite, asserting that the claims are not directed to statutory subject matter.[10] The Examiner also apparently objected to certain of Appellant's claim limitations as not limiting the scope of its claims.[11] Finally, the Examiner concluded that since certain of Appellant's claim limitations allegedly do not limit the structure of Appellant's claimed specimen vessels, the limitations would not be considered.[12]

The MPEP requires that definiteness of claim language be analyzed in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one of ordinary skill in the art at the time of the invention.[13] Figure 5 of Appellant's application illustrates a specimen container supplier, a specimen collection site, and

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[10] Paragraph 4 of Office Action mailed March 29, 2005. ('According to 35 U.S.C. 101, patentable inventions are related to "any new and useful process, machine, manufacture, or composition". It is not clear, which category of this four the claimed subject matter belongs to.').

[11] Id. ('*Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a* ***particular structure*** *does not limit the scope of a claim or claim limitation.*').

[12] Id. ('The examiner concludes that since the location of the vessels does not further limit their structure, the limitation recited in the independent claims after "wherein" does not bear any patentable weight.')

[13] MPEP 2173.02.

a laboratory. One of ordinary skill in the art would appreciate that these elements correspond to Appellant's claimed facilities from reading Appellant's disclosure.[14] It is clear, to answer the examiner, that the claims cover a manufacture, one of the statutory classes. Thus, Appellant states the subject matter it regards as the invention with a *reasonable* degree of clarity and particularity so that one of ordinary skill in the art would understand the scope of the claims.[15]

The Examiner also raised various hypothetical questions,[16] all of which can be addressed by simply reading Appellant's claim language. For example, the Examiner has asserted that, from Appellant's claim language, one would not understand whether a vessel in transport falls within scope of the claim language.[17] Appellant's claims do not claim vessels in transport. One of ordinary skill would understand that the claimed population includes vessels at specified locations that are *transportable* between the locations. Despite the Examiner's protestations, the use of clear functional language to define the scope of protection sought is perfectly acceptable,[18] so long as the language describes subject matter with a *reasonable* degree of clarity and particularity.[19] Potential infringers need to be able to tell if they infringe or not, and they certainly would have no difficulty on that score.

The examiner chooses to disregard the claim recitations that members of the population being claimed are located as defined locations. Such claiming may be unconventional, but it is not non-statutory and the examiner is not free to disregard it. Claims frequently recite elements in various positions, and those positions are attributes of the elements that are given weight in the evaluation of patentability. See generally *Chisum on Patents*, § 18.07[4][c] (2005).

Appellant's claim language is reasonably clear and particular, so that one of ordinary skill would understand the scope of the claimed subject matter. Therefore, Appellant's claims are not

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[14] See, for example, page 8, line 14 – page 9, line 3; page 12, line 25; page 13, line 23; page 14, line 17.

[15] See MPEP §2171 (Emphasis added).

[16] Paragraph 3 of Office Action mailed November 16, 2004; Paragraph 4 of Office Action mailed March 29, 2005.

[17] 'If the vessels are moving and changing their location, how can such a system be definite?' Paragraph 3 of Office Action mailed November 16, 2004; Paragraph 4 of Office Action mailed March 29, 2005.

[18] MPEP§ 2173.01.

[19] See MPEP § 2173.02.

indefinite, and each of the rejections of Claims 1-21 and 40-44 under 35 U.S.C. 112, second paragraph, is improper. The rejection of each claim should be reversed.

C. Petrick does not Anticipate Claims 1-4, 6-7, 9-12, 14-15, 18-19, 21, 38, 41, and 44.

Appellant's claims describe a specimen system that includes a population of collection vessels, each configured to receive and contain a specimen. The population includes members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. The members are transportable between the facilities and the vessels have wireless electronic memory tags attached so that the tags remain as the vessels are transported between facilities.

Petrick discloses a chain of custody form provided with a radio frequency identification chip and further discloses a data collection process achievable with the form. Petrick's process includes recording information on the chip as a sample is transferred to a collection custodian, an intermediate custodian, and a laboratory. Petrick says nothing about a vessel distribution facility, or members of a population of vessels located there.

Petrick anticipates Appellant's claims only if each and every element as set forth in the claim is found either expressly or inherently described in Petrick.[20] The reference does not disclose a population of vessels including members at each of Appellant's specified locations. Therefore, Petrick does not anticipate Claim 9. Moreover, since Petrick is NOT prior art, having been sworn behind, these rejections are improper, and should be reversed.

D. Berney does not Anticipate Claims 1-2, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44.

Berney discloses a system for registering useful information during analyses of blood in conventional glass test tubes 1.[21] Berney's electronic memory labels 4 are attached to supports 31 that are fixed on the test tubes 1 in a testing laboratory at the time of sample analysis.[22] The supports 31 rest on a base 33 including a bus system 46 for transferring information to and from

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[20] MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

[21] Column 1, Line 11 of Berney.

[22] Col 1, Lines 35-38 of Berney; Column 1, Lines 64-65 of Berney; Column 2, Lines 28-29. (Emphasis Added).

the labels 4 during analysis.[23] Berney does not disclose and is not concerned with vessels at a vessel distribution facility, a specimen collection facility and a specimen testing laboratory facility. Instead, Berney's system provides a temporary mount to a test tube during analysis of the test tube contents in a laboratory – only the last of the three locations of applicant's claims.

Berney anticipates Appellant's claims only if each and every element as set forth in the claims is found either expressly or inherently described.[24] The Examiner concludes that Berney inherently discloses Appellant's claimed population of biomedical specimen collection vessels.[25] But, to be inherent, the features of Appellant's claimed invention *must necessarily be* present in the Berney disclosure.[26] Appellant's population of vessels having members at the specified locations is not even consistent with Berney's disclosure, much less, *necessarily present*. One of ordinary skill would read that Berney's labels' attachment to the test tubes is temporary. The labels are attached to the test tubes in the lab and removed in the lab. Accordingly, Berney neither explicitly nor inherently discloses any of Appellant's Claims 1-2, 6-7, 9-10, 14-15, 18-19, 21, 40-41 and 44. The Examiner's rejections of these claims as anticipated by Berney should be reversed.

E. The Examiner Failed to Establish That Claims 5, 8, and 13 are *Prima Facie* Obvious in View of Petrick.

A rejection of a claim in a utility application under 35 U.S.C. § 103(a) based on combinations of prior art references is a legal conclusion which must be based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of obviousness. The references must provide one of ordinary skill a motivation to combine their respective elements to yield the claimed invention. *In Re Dembiczak*, 50 U.S.P.Q. 2d 1614 (Fed. Cir. 1999).

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[23] Col 2, Lines 34-56 and Figures 3 and 4 of Berney.

[24] MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

[25] Paragraph 7 of Office Action dated 3/29/2005.

[26] MPEP § 2112 (IV.).

In the case of *In re Lee*, 61 U.S.P.Q. 2d. 1430, 277 F3d 1338 (Fed. Cir. 2002), the court indicated that the findings under 35 U.S.C. 103 must be based on reasoned findings that one of ordinary skill in the art would have been motivated to select and combine the references. The Court further indicated that the findings and the grounds thereof must be clearly indicated on the record. And the evidence must come from the references, not the examiner's hindsight-based guesswork:

> With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher." W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion. 61 USPQ2d at 1434

The Examiner concludes that it would have been obvious to store data including the identity of a specimen vessel and product information about the vessel on a memory tag. One of ordinary skill would allegedly modify Petrick to include such information 'because vessels (containers) from different suppliers may vary, and therefore such information is important for handling them properly, and because information on a supplier is always conventionally provided with products.[27] The Examiner cited no authority for this position. Subjective belief and unknown authority are not proper substitutes for evidence bearing on the question whether one of ordinary skill would have combined the references to produce Appellant's claimed inventions.[28] In this case, the record is devoid of objective evidence supporting the Examiner's mere conclusory statements. Therefore, the Examiner has failed to establish a *prima facie* case that Claims 5, 8, and 13 would have been obvious in view of Petrick, so the obviousness

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[27] Paragraph 11 of Office Action mailed March 29, 2005.

[28] In re Lee, 277 F.3d at 1342-44, 61 USPQ2d at 1433-34.

rejections should be reversed. Of course, the rejections should also be reversed because Petrick is not prior art.

F. Claims 16, 17, 20, 38, 42, and 43 are not Obvious over Petrick in View of Hoffman.

Hoffman discloses an identification system for determining an individual's biometrics sample and personal identification code gathered during a bid step. The biometrics sample and personal identification code for that individual gathered during a registration step are stored at a remote site wherein there is a data processing center. Biometric input data is preferably encrypted and sealed.

The Examiner asserts that one would combine the electronic signature disclosed in Hoffman with Petrick's disclosure because doing so would be 'an obvious improvement over hand-written document and because electronic submission of the forms suggested by Petrick assumes electronically encoded signature.'[29] But subjective belief and unknown authority are not proper substitutes for evidence of obviousness and thus do not support a *prima facie* case of obviousness.[30] The Examiner has not pointed to objective evidence of obviousness, and has thus failed to show that Claims 16, 17, 20, 38, 42, and 43 would have been an obvious combination of Petrick and Hoffman. Moreover, the proposed elimination of handwritten forms would destroy the very essence of Petrick – a business form that one writes on! Each of these rejections should therefore be reversed, in addition to reversal on the grounds that Petrick is not prior art.

G. Claims 2 and 10 are Patentable over Berney in view of RD 421048A.

To establish a *prima facie* case of obviousness, a combination of prior art references must teach or suggest all the limitations of the allegedly obvious claimed invention.[31] Berney does not teach or suggest a specimen system including a population of vessels having members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. RD 421048A discloses a method for chemical management for tracking compounds within a

[29] Paragraph 12 of Office Action mailed March 29, 2005.

[30] In re Lee, 277 F3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002).

[31] MPEP 2143 citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

chemical synthesis system including identification tags having passive transponders.[32] Modifying Berney to include RD 421048A's passive transponders does not produce the diagnostic specimen system of Appellant's Claims 2 and 10. RD421048A still does not disclose applicant's claimed vessel locations. Thus, the Examiner has also failed to establish a *prima facie* case of obviousness of Claims 2 and 10. So, the rejection of each of Claims 2 and 10 as obvious over Berney in view of RD 421048A should also be reversed.

H. Claims 1, 6-7, 9-10, 14-15, 18-19, and 21 are Patentable over Berney in View of Bowman.

1. To establish a *prima facie* case of obviousness, a combination of prior art references must teach or suggest all the limitations of the allegedly obvious claimed invention.[33] The examiner cites Bowman's chain of custody bag 10 including a removable specimen label 28. Neither Berney nor Bowman teaches or suggests a specimen system including a population of vessels having members located at a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory. Therefore, each of Claims 1, 6-7, 9-10, 14-15, 18-19, and 21 is in condition for allowance. The rejection of each of these claims should be reversed.

2. Claims 18, 19 and 21 argued separately.

Furthermore, the methods described by Claims 18, 19, and 21 of Appellant's application are not *necessarily* present in either reference, and are thus not inherently disclosed and should be allowed.[34]

I. Claims 3-4 and 11-12 are Patentable over Berney in View of Bowman, and Further in View of Stevens.

Stevens discloses a sample collection tube 20 and a label 40 comprising a permanent portion 50 having a barcode 90 and a peel away portion 70 for affixation to a test request form or to another container or item.[35] The Examiner asserts that it would have been obvious to combine

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[32] RD 421048 A at ABSTRACT.

[33] MPEP 2143 citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

[34] MPEP § 2112 (IV.).

[35] Stevens at column 5, lines 25-27; column 6, lines 19-21; Figure 8.

the barcode of Stevens with a version of Berney having a modified electronic tag by adding a label "to 'create a link between the container, the patient, and the test request forms', or any other forms associated with using this container."[36] Berney discloses an electronic label that that provides for registration of *all* useful information required for analysis of a blood sample, however, and thus *eliminates* the need for jotting down and manual transfer of information.[37] Combining Stevens' barcode associated with a manual entry form or another container with the Examiner's modified version of Berney would destroy Berney's purpose of eliminating manual entry of information. Also, the result would still not have vessels at applicant's recited locations. Thus, one of ordinary skill would not modify the references as proposed by the Examiner.[38] Accordingly, the obviousness rejection of each of Claims 3-4 and 11-12 is improper and should be reversed.

J. Claims 5 And 13 Are Patentable Over Berney in View of Bowman and Stevens, and Further in View of Leuenberger.

Leuenberger discloses a microporous plastic film label 12 for a blood pack 10. The reference also discloses supplying a manufacturer's product code and lot number with blood packs.[39] The Examiner asserts that it would have been obvious to include such information on Petrick's electronic memory labels "because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and because information on a supplier is always conventionally provided with products,"[40] despite the absence of a suggestion arising from the references to store product information on Berney's electronic memory tags. Berney's label is affixed to a test tube and data entered during the time of analysis in a testing laboratory.[41] Berney's system does not attach the tag until the test tube is in the lab, and presumably already contains a specimen. Information about the specimen and its

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[36] Paragraph 15 of Office Action mailed March 29, 2005 quoting Bowman at Column 1, Line 13-18.

[37] Berney at column 1, lines 30-32.

[38] MPEP 2143.

[39] Leuenberger at column 1, lines 17-18.

[40] Paragraph 16 of Office Action mailed March 29, 2005.

[41] Berney at Column 1, Lines 34-38.

evaluation is what is important to Berney, not the maker of the test tube. (See Col. 1, line 65 – Col. 2, line 2) One of ordinary skill would have no reason to enter test tube product information on Berney's labels at the testing laboratory. Therefore, one of ordinary skill would not store the product information disclosed in Lueunberger on the electronic memory tags disclosed in Berney, and Appellant's Claims 5 and 13 are both in condition for allowance.

K. Claim 8 is Patentable over Berney, Bowman, RD421048A, Stevens and Leuenberger.

The Examiner further asserts that it would have been obvious to include product information on a thrice-modified version of Berney 'because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container.'[42] Neither of these proffered motives, however, explains why one would be motivated to store supplier information *on an electronic memory tag*, as Appellant claims. Thus, they are merely unsupported allegations that fail to address the question whether one of ordinary skill would have been motivated to combine the references to produce the *claimed invention.* Arguments made above are also applicable here. Therefore, the Examiner has failed to present a *prima facie* case of obviousness with respect to Claim 8, and the rejection of this claim should be reversed.

L. The Examiner Failed to Establish That Claims 16, 20,and 38 are Prima Facie Obvious over Berney in View of Bowman, and Further in View of Fukuzaki.

These claims recite the inclusion of an electronic signature of a donor of a toxicology specimen.

Fukuzaki discloses an electronic document security system including means for modifying a seal or signature with characteristic data of the document.[43] The Fukuzaki electronic signature is for use on documents transmitted by electronic means. The Examiner concludes that information contained on an electronic label attached to a toxicology specimen should be secured, and that Fukuzaki provides "the most convenient way of securing the

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[42] Paragraph 17 of Office Action mailed March 29, 2005.

[43] Fukuzaki at column 2, lines 29-34.

information."[44] Thus, where Fukuzaki says to send signatures electronically, the examiner adds a dollop of hindsight without reference to a motivation derived from the references to say it also would be convenient and obvious for tags affixed to toxicology specimen containers. This proffered motivation to combine Berney modified by Bowman with Fukuzaki is nothing more than a subjective belief based on unidentified authority that fails to provide an evidentiary support for the rejections of Claims 16, 20 and 38. Accordingly, the Examiner has failed to present a proper *prima facie* case of obvious with regards to Claims 16, 20 and 38, so each of the rejections should be reversed.

M. Claim 17 is Patentable over Berney in view of Bowman, RD 421048 A, Stevens, Leuenberger, Fukuzaki and Coli.[45]

Subjective belief and unknown authority are not proper substitutes for objective evidence of obviousness.[46] In rejecting Claims 17 of the application as describing an invention that would have been obvious to one of ordinary skill in the art, the Examiner merely recycles the same unsupported conclusory statements previously shown to be improper.[47] Accordingly, the Examiner has failed to present a proper *prima facie* case of obvious with regards to Claims 17, and this rejection should be reversed.

The Examiner's rejection of Claims 1-21, 38, 40-44 should be reversed.

Respectfully submitted,

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[44] Paragraph 18 of Office Action mailed March 29, 2005.

[45] Although Coli is listed as a reference upon which the rejection of Claim 17 was based in Paragraph 19 of the Office Action mailed March 29, 2005, the examiner does not explain why Coli is cited against Claim 17.

[46] In re Lee, 277 F.3d at 1342-44, 61 USPQ2d at 1433-34.

[47] Paragraph 19 of Office Action mailed March 29, 2005.

Date: November 17, 2005
File No.: 2552-011

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS DOCUMENT IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL, IN AN ENVELOPE ADDRESSED TO: **COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450**, ON November 17, 2005
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Christian E. Carter-Seyboth
Name of Depositor

Christian E. Carter-Seyboth
Signature

November 17, 2005
Date of Signature

8. Claims Appendix

The appealed claims are as follows:

1. A diagnostic specimen system comprising a population of biomedical specimen collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

2. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag includes a radio frequency transponder.

3. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including an identification code for the vessel.

4. A diagnostic specimen system as claimed in claim 3 further including a label imprinted with a bar code attached to each vessel, the bar code identifying the vessel.

5. A diagnostic specimen system as claimed in claim 1 wherein each electronic memory tag contains stored data including the identity of a supplier of the vessel and product information about the vessel.

6. A diagnostic specimen system as claimed in claim 1 wherein an electronic memory tag contains stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

7. A diagnostic specimen system as claimed in claim 6 wherein an electronic memory tag contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

8. A diagnostic specimen system comprising:

a population of collection vessels located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities;

data stored on an electronic memory tag including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, and definition of the analytical tests to be performed on the specimen in the vessel; and

a label imprinted with an identifying bar code attached to each vessel.

9. A toxicology specimen system comprising a population of collection vessels, each configured to receive and contain a toxicology specimen and having a wireless electronic memory tag attached to the vessel for non-contact storage and retrieval of information, wherein

the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory, wherein each of the collection vessels includes a wireless electronic memory tag for non-contact storage and retrieval of information attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities.

10. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag includes a radio frequency transponder.

11. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including an identification code for the vessel.

12. A toxicology specimen system as claimed in claim 11 further including a label imprinted with an identifying bar code attached to each vessel.

13. A toxicology specimen system as claimed in claim 9 wherein each electronic memory tag contains stored data including the identity of the supplier of the vessel and product information about the vessel.

14. A toxicology specimen system as claimed in claim 9 wherein an electronic memory tag contains stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

15. A toxicology specimen system as claimed in claim 14 wherein an electronic memory tag contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

16. A toxicology specimen system as claimed in claim 9 wherein an electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen.

17. A toxicology specimen system comprising:

a population of biomedical specimen collection vessels, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility, each vessel having a wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is transported between facilities, the electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information; data stored on the electronic memory tags including an identification code for the vessel, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and a label imprinted with an identifying bar code attached to each vessel.

18. A method for electronically storing information on a diagnostic or toxicology specimen vessel and remotely reading information from the vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached thereto, wherein the population includes members located at and transportable between a vessel distribution facility, a specimen collection facility, and a specimen testing laboratory facility;

electronically storing data on one of the electronic memory tags at the vessel distribution facility;

shipping members including the electronic memory tags attached thereto with electronically stored data from the vessel distribution facility to the specimen collection facility; and

reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner at a specimen testing laboratory facility.

19. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached to the vessel at a vessel distribution facility;

distributing population members including the wireless electronic memory tag attached thereto to a specimen collection facility;

collecting a specimen from a donor in the specimen container at the specimen collection facility; and

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag.

20. A method as claimed in claim 19 further including collecting and storing an electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

21. A method as claimed in claim 19 further including transporting the member vessel with collected specimen from the specimen collection facility to a specimen testing laboratory and storing the results of the analytical tests performed on the specimen in the vessel on the electronic memory tag at the specimen testing laboratory.

22. – 37 (Canceled).

38. A toxicology specimen system comprising a collection vessel configured to receive and contain a toxicology specimen, a tamper-indicating seal, and wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is transported, the tag for non-contact storage and retrieval of information and wherein the electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen.

39. (Canceled).

40. A diagnostic specimen system as claimed in claim 1 further including an electronic database accessible from the specimen collection facility for storing data entered at the collection facility.

41. A diagnostic specimen system as claimed in claim 40 further including an electronic network connecting the specimen collection facility to the specimen testing laboratory for transmitting data from the collection facility to the testing laboratory.

42. A toxicology specimen system comprising a population of collection vessels, each configured to receive and contain a toxicology specimen and having a wireless electronic memory tag attached to the vessel for non-contact storage and retrieval of information, the memory tag containing stored data including an encoded electronic signature of the donor of a toxicology specimen, wherein the population includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility and wherein the members are transportable between the facilities and the tag is attached to the vessel such that it remains attached to the vessel as the vessel is transported between facilities.

43. A toxicology specimen system comprising:

a biomedical specimen collection vessel and a tamper-indicating, wireless electronic memory tag attached to the vessel such that the tag remains attached to the vessel as the vessel is shipped to between a between a vessel distribution facility, a specimen collection facility, and a

specimen testing laboratory facility, the tag including a radio frequency transponder for non-contact storage and retrieval of information;

data stored on the electronic memory tag including an identification code for the container, the identity of the supplier of the vessel and product information about the vessel, identifying information about a specimen contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and

a label imprinted with an identifying bar code.

44. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen vessel comprising:

providing a population of biomedical specimen vessels, each having a wireless electronic memory tag attached to the vessel, wherein the population includes a member at a vessel distribution facility, a member at a specimen collection facility, and a member at a specimen testing laboratory facility, and wherein each of the vessels includes a wireless electronic memory tag attached thereto such that the tag remains attached to the vessel as the vessel is transported between facilities;

collecting a specimen from a donor in the specimen vessel at the specimen collection facility;

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag; and

collecting and storing the electronic signature of the specimen donor on the electronic memory tag at the specimen collection facility.

9. Evidence Appendix

A. These references were cited by the Examiner in making rejections, and applicant relies on portion of them to show the errors of the rejections. Copies are attached.

Patent Number or Document Number	1st Named Inventor	Examiner Cited in Office Action Dated
6,535,129	Petrick	29 March 2005
5,613,012	Hoffman	29 March 2005
5,777,303	Berney	29 March 2005
5,135,313	Bowman	29 March 2005
EP 1,004,359 A2	Stevens	29 March 2005
5,314,421	Leuenberger	29 March 2005
RD 421048 A		29 March 2005

B. Additional evidence submitted by applicant.

Declarations under Rule 1.131 of Jason Bowman, Danny Charles Bowman and David Michael Lewis, and Exhibits thereto. Copies are attached.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny Charles Bowman

Serial No.: 09/737,185 Examiner: Gakh

Filed: December 14, 2000 Art Unit: 1743

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER RULE 1.131

DANNY CHARLES BOWMAN does hereby say as follows:

1. I am one of the inventors of the above-identified patent application.

2. I have attached copies of evidence that the above-identified patent application was conceived in the United States or a NAFTA country before November 17, 2000 and applicants were diligent to a constructive redirection to practice from a time prior to November 17, 2000, until December 14, 2000. Dates not specified herein have been redacted but were prior to November 17, 2000:

a. a draft of the application for the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES was developed with the assistance of applicants' lawyers by a date prior to November 17, 2000, and a copy is the attached Exhibit A;

b. a final draft with formal documents for signature was forwarded by counsel on December 5, 2000;

c. The inventors reviewed and approved the application for filing, and the formal documents accompanying the application were signed December 11, 2000, and forwarded to counsel for filing in the PTO on December 14, 2000.

d. from the period beginning at the latest when the "final draft" of the application was developed prior to November 17, 2000 until December 14, 2000, when the application was filed, the inventors of the subject matter of the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES proceeded diligently in all matters regarding the filing of the application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Danny Charles Bowman

6/01/04

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny Charles Bowman

Serial No.: 09/737,185 Examiner: Gakh

Filed: December 14, 2000 Art Unit: 1743

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER RULE 1.131

DANNY CHARLES BOWMAN does hereby say as follows:

1. Richard Kimberly Paisley is one of the inventors of the above-identified patent application.

2. Richard Kimberly Paisley assigned the above-identified patent application to GBF, Inc.

3. I am an officer of GBF, Inc.

4. Richard Kimberly Paisley in unavailable to GBF, Inc. to provide a Declaration Under Rule 1.131.

5. I am one of the inventors of the above-identified patent application.

6. I have attached copies of evidence that the above-identified patent application was conceived in the United States or a NAFTA country before November 17, 2000 and applicants were diligent to a constructive redirection to practice from a time prior to November 17, 2000, until December 14, 2000. Dates not specified herein have been redacted but were prior to November 17, 2000:

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d. from the period beginning at the latest when the "final draft" of the application was developed prior to November 17, 2000 until December 14, 2000, when the application was filed, the inventors of the subject matter of the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES proceeded diligently in all matters regarding the filing of the application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Danny Charles Bowman

6-15-04

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny Charles Bowman

Serial No.: 09/737,185 Examiner: Gakh

Filed: December 14, 2000 Art Unit: 1743

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER RULE 1.131

JASON BOWMAN does hereby say as follows:

1. I am one of the inventors of the above-identified patent application.

2. I have attached copies of evidence that the above-identified patent application was conceived in the United States or a NAFTA country before November 17, 2000 and applicants were diligent to a constructive redirection to practice from a time prior to November 17, 2000, until December 14, 2000. Dates not specified herein have been redacted but were prior to November 17, 2000:

a. a draft of the application for the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES was developed with the assistance of applicants' lawyers by a date prior to November 17, 2000, and a copy is the attached Exhibit A;

b. a final draft with formal documents for signature was forwarded by counsel on December 5, 2000;

c. The inventors reviewed and approved the application for filing, and the formal documents accompanying the application were signed December 11, 2000, and forwarded to counsel for filing in the PTO on December 14, 2000.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Jason Bowman

6/2/2004

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Danny Charles Bowman

Serial No.: 09/737,185 Examiner: Gakh

Filed: December 14, 2000 Art Unit: 1743

For: **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER RULE 1.131

DAVID MICHAEL LEWIS does hereby say as follows:

1. I am one of the inventors of the above-identified patent application.

2. I have attached copies of evidence that the above-identified patent application was conceived in the United States or a NAFTA country before November 17, 2000 and applicants were diligent to a constructive redirection to practice from a time prior to November 17, 2000, until December 14, 2000. Dates not specified herein have been redacted but were prior to November 17, 2000:

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b. a final draft with formal documents for signature was forwarded by counsel on December 5, 2000;

c. The inventors reviewed and approved the application for filing, and the formal documents accompanying the application were signed December 11, 2000, and forwarded to counsel for filing in the PTO on December 14, 2000.

d. from the period beginning at the latest when the "final draft" of the application was developed prior to November 17, 2000 until December 14, 2000, when the application was filed, the inventors of the subject matter of the PAPERLESS CHAIN OF CUSTODY FOR LAB SAMPLES proceeded diligently in all matters regarding the filing of the application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.

David Michael Lewis

6/3/04
Date

****
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****

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RESULT	OK

Rhodes & Mason

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Original Will Follow Via:

☐ Mail
☐ Hand Delivery
☐ Without Enclosures
☐ Courier
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TELEFAX COVER SHEET

TO: Mr. Danny Bowman	FROM: Art MacCord
ORGANIZATION/FIRM: GBF, Inc.	DATE: November 9, 2000
FAX NUMBER: (336) 665-0209	RECIPIENT'S PHONE NUMBER: (336) 665-0205
TOTAL # OF PAGES (Including Cover): 31	YOUR E-MAIL ADDRESS: amaccord@rhodesmason.com

RE: Paperless Chain of Custody Evidence for Lab Samples

EXHIBIT A –

Rhodes & Mason

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TO: Mr. Danny Bowman	FROM: Art MacCord
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FAX NUMBER: (336) 665-0209	RECIPIENT'S PHONE NUMBER: (336) 665-0205
TOTAL # OF PAGES (Including Cover): 31	YOUR E-MAIL ADDRESS: amaccord@rhodesmason.com
RE: Paperless Chain of Custody Evidence for Lab Samples	

NOTES/COMMENTS:

Christian Carter
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via fax

November 9, 2000

Mr. Danny Bowman
GBF, Inc.
P. O. Box 18744
Greensboro, NC 27419

Re: **Paperless Chain of Custody Evidence for Lab Samples**
Our File No. 2552-011

Dear Danny:

Enclosed is a final draft of the subject patent application. Please review the application and provide your comments. Also, I left a voice-mail message today requesting identification of the inventors of your invention. Once we have your comments and the names and addresses of the inventors, we will prepare the necessary documents for submittal of your application to the PTO.

Sincerely,

Art MacCord

HAM/CHP/cc

28025

Rhodes & Mason

ATTORNEYS AT LAW

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December 5, 2000

Mr. Danny Bowman
GBF, Inc.
410-J Gallimore Dairy Road
P.O. Box 18744
Greensboro, NC 27419

Re: **Patent Application for PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES**
Our File No. 2552-011

Dear Danny:

Enclosed is the above-identified utility patent application, including Inventor's Declaration; drawings; Assignment; Power of Attorney; and Small Entity Form, which are ready for signature.

The inventors should carefully review the text, Inventor's Declaration, drawings and Assignment. If any minor changes need to be made, they may be made in permanent ink with the inventors' initials and the date in the adjacent margin. No changes may be made once the application has been signed. If major changes are needed, please mark up the application as needed and return it to me for preparation of a freshly printed text.

Once the application is in good form, please sign and date at all places marked with a red "x." Have an officer of the company review and sign the Power of Attorney. After signing and dating, please return all of the application papers to us for filing with the Patent and Trademark Office (PTO).

Exhibit B

Also enclosed is an Important Legal Notice, which briefly describes the Duty of Candor owed to the PTO by patent applicants. If it suggests anything that needs to be submitted to the PTO that I don't already know about, please let me know.

I appreciate your allowing us to be of service to you.

Sincerely,

Art MacCord

AM/CHP/cc/ls
Enclosures

IMPORTANT INFORMATION FOR PATENT APPLICANTS

To: Inventors

Subject: The Requirements of United States Patent Law

ALL OF US INVOLVED WITH THIS APPLICATION ARE CHARGED WITH A DUTY OF CANDOR AND GOOD FAITH TOWARD THE PATENT EXAMINER. This means we must comply with regulations which require us to disclose all material information we are aware of having a bearing on the patentability of your invention.

INFORMATION IS MATERIAL IF IT, BY ITSELF OR WITH ANOTHER ITEM OF INFORMATION, DISCLOSES OR SUGGESTS THE INVENTION OR IS OTHERWISE INCONSISTENT WITH STATEMENTS WE ARE MAKING TO THE PATENT OFFICE. Information such as prior art having a bearing on the patentability of your claimed invention would therefore be material. Prior art may include:

a) articles, patents, product announcements, technical reports, lectures or other material of others which might be considered as pertaining to your invention published prior to your date of invention;

b) any public use or demonstration of your invention or of apparatus or methods which might be considered as pertaining to your invention more than one year before your application is filed;

c) any sale or offer for sale of products incorporating your invention or made by its use more than one year before your application is filed;

d) any commercial machine or product of which your invention is an improvement;

e) any pertinent prior work of others (except fellow employees) of which you have knowledge.

IT IS ESSENTIAL THAT ALL ITEMS NOTED ABOVE, AS WELL AS ANY OTHER INFORMATION YOU BELIEVE MAY HAVE A BEARING ON THE NEWNESS OR OBVIOUSNESS OF THE CLAIMED INVENTION, BE BROUGHT TO OUR ATTENTION PROMPTLY. We can review the information to determine if the law requires its disclosure to the Patent Examiner. In this manner, you can satisfy your duty of disclosure and we can insure that all material information is disclosed to the U.S. Patent and Trademark Office. This also works to the patent owner's benefit because a more thoroughly examined patent is less subject to attack later on.

PTO/SB/10 (1-99)
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(c))—SMALL BUSINESS CONCERN	Docket Number (Optional) 2552-011

Applicant, Patentee, or Identifier: Danny Bowman, et al.

Application or Patent No.:

Filed or Issued:

Title: PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES

I hereby state that I am

☐ the owner of the small business concern identified below:

☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN GBF, Inc.

ADDRESS OF SMALL BUSINESS CONCERN 410-J Gallimore Dairy Road, Post Office Box 18744,

Greensboro, NC 27419

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 20416.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

☒ the specification filed herewith with title as listed above.

☐ the application identified above.

☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below:

☒ no such person, concern, or organization exists.

☐ each such person, concern, or organization is listed below.

Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING Danny Bowman

TITLE OF PERSON IF OTHER THAN OWNER President

ADDRESS OF PERSON SIGNING 410-J Gallimore Dairy Road, P.O. Box 18744, Greensboro, NC 27419

SIGNATURE ✓ DATE ✓

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bowman, et al.
For: PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES
Filed concurrently herewith.
Serial Number to be assigned.

Commissioner for Patents
Washington, D.C. 20231

POWER OF ATTORNEY

Sir:

The undersigned, assignee of the entire interest in and to an application of Bowman, et al. for U.S. Letters Patent for PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES, by an assignment document being recorded contemporaneously herewith, hereby appoints the firm of Rhodes & Mason, P.L.L.C., comprising C. Robert Rhodes, Reg. No. 24,200, Edward W. Rilee, Reg. No. 31,869, Howard A. MacCord, Jr., Reg. No. 28,639, Jack B. Hicks, Reg. No. 34,180, James L. Lester, Reg. No. 38,721, William J. Mason, Reg. No. 22,948, Gilbert J. Andia, Jr., Reg. No. 38,815, Jeffrey R. McFadden, Reg. No. 46,916, Benjamin S. Withrow, Reg. No. 40,876, Amy H. Fix, Reg. No. 42,616, Stanislav Antolin, Reg. No. 34,979, and Lewis S. Rowell, Reg. No. 45,469, as my attorneys and/or agents with full power of substitution and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the Patent and Trademark Office connected therewith.

Furthermore, in accordance with 37 CFR §3.73(b), the undersigned hereby states that the documentary evidence of a chain of title from the original owner to the assignee, i.e. assignment

ASSIGNMENT

This Assignment made by us, Danny Bowman, a citizen of the United States of America, residing at 3901 Gaston Road, City of Greensboro, County of Guilford, State of North Carolina, and Jason Bowman, a citizen of the United States of America, residing at 6202 Clarkwood Circle, City of Greensboro, County of Guilford, State of North Carolina, and Mike Lewis, a citizen of the United States of America, residing at 5582 Anson Road, City of Greensboro, County of Guilford, State of North Carolina, and Kim Paisley, a citizen of the United States of America, residing at 2500 Baytree Drive, City of Greensboro, County of Guilford, State of North Carolina, hereinafter referred to as assignors.

WITNESSETH: That,

WHEREAS, we are the joint inventors of certain new and useful improvements in **PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES** for which we are about to make application for Letters Patent of the United States, and for which we have executed a declaration on the X_____ day of X_____, 2000.

WHEREAS, GBF, Inc., a corporation duly organized and existing under the laws of the State of North Carolina and having a principal place of business in Greensboro, County of Guilford, State of North Carolina, hereinafter referred to as assignee, is desirous of acquiring the entire right, title and interest in and to said invention as described in the specification executed by us concurrently herewith, and any and all Letters Patent which shall be granted therefor;

NOW, THEREFORE, To All Whom It May Concern, be it known that for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, we, the said assignors, have sold, assigned, transferred and set over unto the said assignee, its successors and assigns, the entire right, title and interest in and to the above-mentioned application and

PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES

BACKGROUND OF THE INVENTION

The present invention relates to improvements in identification, logistics control, and information management for biomedical specimens collected for diagnostic or toxicology testing. Diagnostic and toxicology specimens are typically collected for analytical testing from donors at collection sites such as hospitals, clinics, or doctors' offices. These specimens are collected in primary specimen containers specifically designed to completely and safely contain the specimens during handling and shipment in order to preserve the integrity of the specimens and to protect the health of persons who come in contact with the containers. In addition, primary toxicological specimen containers are typically provided with tamperproof locks or seals to ensure that the integrities of the toxicological specimens are not breached by unauthorized persons or by mishandling of the containers.

Diagnostic and toxicology testing requires the collection, recording, and maintenance of essential information about each diagnostic or toxicology specimen. Such information includes the identity and nature of each specimen, the identity of the specimen donor, the test or tests to be performed on the specimen, the identity of the person collecting the sample, the time and place of collection, and the results of tests performed on the specimen. Also, toxicology specimens typically require written authorizations signed by their donors. Because most specimen collection sites do not have testing laboratories on site, the specimens are typically sent to remote reference laboratories. Accordingly, the pertinent information about a particular specimen must be accurately communicated to the laboratory which tests the specimen, and the laboratory must in turn accurately report the test results for that specimen back to the site where the specimen was originally collected or to another remote site.

The recording, maintenance, and communication of specimen and testing information is currently done using preprinted duplicate-page forms having spaces for manually entering designated information onto the forms. Duplicate copies of the completed forms are used for communicating and recording information among and between multiple departments or sites involved with the handling or testing of a specimen. It is common for such forms to have sequential numbers and bar codes that correspond to matching bar coded labels which can be affixed to the specimen containers corresponding to the written information on the associated forms. These bar codes can be scanned to identify the specimens contained in the bar-coded containers, and the bar codes on the forms can be scanned to correlate the recorded information with the specimen. In addition, written or typed information is often included on labels on the specimen containers to show details about the contained specimens. The primary specimen containers and copies of the associated forms are typically maintained together by placing them together in secondary containers such as boxes or sleeves. These secondary containers are then transported to a reference laboratory to conduct the required tests on the specimens.

Particularly for toxicology specimens such as urine specimens to be tested for illicit drugs, legal evidence linking the specimen to be tested to the donor is critical. Prior efforts to assure this linkage include chain of custody bags and forms taught in U.S. Patents 5,135,313 to Bowman and 4,873,193 to Jensen et al., and British Patent Application 2,221,208.

Because the specimens originate from multiple remote collection sites, the collection and delivery of such specimens requires coordination between the collection sites, the laboratory, and a courier. Because many collection sites have only a sporadic need for diagnostic or toxicology testing, it is often inefficient for a designated courier to visit a potential collection site daily or semi-daily to possibly collect specimens for delivery. In order to avoid such inefficiency, collection sites must typically notify either the laboratory or

a courier each time specimens are awaiting collection for delivery to the laboratory, causing a different type of inefficiency.

Modern reference laboratories typically include automated handling and testing equipment. Such laboratories have automated sorters and conveyors for routing specimens to testing stations and testing equipment that automatically performs the required tests on the specimens with minimal manual human intervention. However, even such automated laboratories must receive and inventory specimens from remote specimen collection sites by manually unpacking each specimen and the associated forms from their boxes or sleeves. The laboratories typically use manual bar code scanners to individually scan the bar code labels on the received specimen containers and forms and then manually input data into computers that control the automated handling and testing equipment. The specimens are manually staged for introduction into the automated systems. Once testing has been performed on a specimen, a laboratory typically records the test results manually on the associated forms and then reports the test results by sending the completed forms to the originating specimen collection site or other selected destination.

As can be appreciated by those skilled in the art, the current methods for information management and logistical control for biological specimens collected for diagnostic or toxicology testing include a number of difficulties. The use of written forms and written labels to record, maintain, and communicate specimen information is especially problematic. Manual entry of information onto forms or labels at collection sites and laboratories is labor intensive and causes delays in processing the specimens and information. Also, written forms or labels may be illegible or may become obliterated by handling or spills, causing a loss or miscommunication of essential information. Furthermore, it is necessary to physically maintain copies of the forms with the associated specimens. These forms add bulk to transport packaging for the specimen containers, and may be lost or dissociated from the

specimens. In addition, the forms must be individually handled and scanned or read when received by a reference laboratory, adding labor cost and causing delays leading to underutilization of the automated laboratory handling and test equipment. Lost or dissociated forms may cause potentially harmful delays in the testing or reporting of diagnostic test results for distressed donors experiencing medical emergencies. In addition, if a form containing an authorization signature of a toxicology specimen donor is lost or misplaced, the test cannot be performed until the donor again authorizes the test.

While the use of bar codes has proved useful for the identification, control, and correlation of specimens and specimen forms, it has not eliminated the need for written forms to record and manage specimen information nor the associated problems. In addition, the bar codes on specimens and forms must be individually scanned and convey only limited basic identity information about the specimens.

Also, because independent specimen collection sites may generate specimens only sporadically, the process of collecting specimens from these sites is problematic. Having couriers regularly visit sites having no specimens for collection wastes labor and transportation costs. Alternatively, having the sites request collection on a case-by-case basis is labor intensive and subject to communication delays or miscommunication.

Accordingly, there is a need in the art for an improved system for managing information for biomedical specimens collected for diagnostic or toxicology testing and for coordinating the relay of specimens between remote collection sites and reference laboratories.

The present invention uses electronic memory tags on diagnostic or toxicology specimen containers to meet this need. Radio Frequency Identification (RFID) systems featuring so-called "smart tags" or "smart labels" and the associated electronic devices for remotely writing information to and reading information from these smart tags or labels are

known. Similar electronic tags were developed by the United States National Laboratory at Los Alamos, NM for the Department of Agriculture to identify and track livestock animals. One supplier, Texas Instruments, Inc., markets such RFID products and systems under the trademark TAG-IT®. As this technology has developed, RFID systems have been used to address a number of needs. For example, U.S. Patent No. 4,912,471 to Tyburski, et al. and U.S. Patent No. 5,351,052 to D'Hont, et al. disclose the use of RFID systems for the identification of and communication between moving vehicles such as automobiles or railroad cars. Also, U.S. Patent Nos. 5,030,807 issued to Landt, et al., 5,971,437, issued to Sakashita, and 6,019,394, issued to Chenoweth disclose the use of RFID systems for identification and control of various moveable objects. However, RFID devices and systems have not been used in connection with diagnostic or toxicological specimen containers for identification and control of biomedical specimens and to improve the management of the information associated with such specimens.

SUMMARY OF THE INVENTION

The present invention fulfills this need in the art by providing a diagnostic specimen container including a collection vessel and a wireless electronic memory tag for non-contact storage and retrieval of information. Preferably, the electronic memory tag includes a radio frequency transponder. The diagnostic specimen container preferably includes data stored on the electronic memory tag including an identification code for the container. Other pertinent information may also be stored on the electronic memory tag, such as the identity of the supplier of the container and product information about the container, identifying information about a specimen contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, or any other relevant data. Desirably, the diagnostic specimen container also includes a label imprinted with an identifying bar code.

The invention also provides a toxicology specimen container including a collection vessel and a wireless electronic memory tag for non-contact storage and retrieval of information.

In one embodiment, the tag contains only a readable identification code so that the container (whether for diagnostic or toxicological specimens) may be simply identified as unique. A computer record may correlate the identification code with the other pertinent information about the specimen.

The invention also provides a method for electronically storing information on a diagnostic or toxicology specimen container and remotely reading information from the container. This method includes providing a specimen container having a wireless electronic memory tag, electronically storing data on the electronic memory tag, and reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner. This method provides for the storage and retrieval of a large amount of data directly onto and from the container without physical contact.

The invention further provides a method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen container including providing a specimen container having a wireless electronic memory tag, collecting a specimen from a donor in the specimen container, and electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag. Preferably, this method includes collecting and storing the electronic signature of the specimen donor on the electronic memory tag. This method may also include storing the results of the analytical tests performed on the specimen in the container on the electronic memory tag.

The invention also provides a method for managing the gathering of diagnostic and/or toxicology specimens from multiple specimen collection sites and the delivery of the

collected specimens to a reference laboratory. The method includes collecting identity and test data for specimens and specimen donors at multiple collection sites, entering the collected data into collection site computer databases, and transmitting the collected data from the collection site computer databases to a computer at a reference laboratory by an internet connection. Then, the method proceeds by compiling and processing the transmitted data with the laboratory computer to generate a schedule and route for gathering the specimens from the specimen collection sites, gathering the specimens from the specimen collection sites according to the schedule and route, and delivering the specimens to the reference laboratory. Preferably, the data collection includes reading information from electronic memory tags attached to containers containing the specimens by scanning the electronic memory tags with an electronic reader/scanner. Desirably, the data collection also includes scanning bar codes imprinted on labels on the specimen containers. The data collection and entry also preferably includes collecting data into an electronic recording device and uploading the recorded information from the electronic recording device into a local computer at each specimen collection site for storage and transmission. Data collection and entry with the electronic recording device may also include collecting the electronic signatures of specimen donors and entering the electronic signatures of the specimen donors into the local computer database.

The invention also provides a method for controlling the receipt, routing, and testing of diagnostic or toxicology specimens at an automated reference laboratory. This method includes delivering diagnostic and/or toxicology specimens to the automated reference laboratory which are contained in specimen containers having specimen and testing information stored on radio frequency memory tags affixed to the specimen containers. The method includes scanning and reading the specimen and testing information from the electronic memory tags on the specimen containers with electronic scanners or readers,

transmitting the information to a microprocessor for controlling the automated laboratory equipment, processing the read information with the microprocessor, and using the processed information to control the sorting, routing, and analytical testing of the specimens by the automated laboratory equipment. The method may also include electronically writing the results of the analytical test or tests for each analyzed specimen to the electronic memory tag on the specimen container containing the corresponding analyzed specimen. This method may also include electronically storing the results of the analytical test or tests and the corresponding specimen identification data on a laboratory computer database. Preferably, the analytical test results data and corresponding specimen identification data stored on the laboratory computer database are transmitted to the corresponding original specimen collection site by an internet connection. Alternatively or in addition, the analytical test results and corresponding specimen identification data stored on the laboratory computer database may be printed to a written test results report.

The invention also provides an integrated method for managing the collection, control, and testing of diagnostic and/or toxicology specimens and for managing the specimen and testing information associated with such specimens. First, encoded specimen containers having electronic memory tags with electronic specimen identification codes stored therein and having bar code labels imprinted with identifying bar codes are provided. Next, the electronic specimen identification code and identifying bar code for each encoded specimen container are correlated and the correlated codes are stored on a central computer database. The encoded specimen containers are then supplied to multiple specimen collection sites and are used to collect specimens from specimen donors at these sites. After gathering data about the collected specimens, specimen donors, and prescribed specimen tests at the specimen collection sites, the data is correlated with the identifying bar codes on the corresponding specimen containers and entered into the collection site computer record.

Next, the gathered and stored specimen, donor, and testing data and correlated identity codes are transmitted from the collection site computer to a laboratory computer at an automated reference laboratory, such as by an internet connection.

The received data is then processed at the reference laboratory, and a queue is defined for specimens awaiting collection for delivery to the automated reference laboratory. This queue is used to define a route for collecting the specimens from the specimen collection sites for delivery to the automated reference laboratory. The specimens are then gathered from the specimen collection sites according to the route, and the collected specimens are delivered to the automated reference laboratory. At the reference laboratory, the electronic memory tags on the delivered specimen containers are electronically interrogated to detect the associated electronic identity codes, and the read data is correlated with the specimen data previously transmitted to the laboratory computer database. The specimens are then automatically sorted for testing, and testing schedules are established using the correlated specimen and testing data in the laboratory computer database. Next, the specimens are automatically routed through the automated reference laboratory using the correlated specimen and testing data in the laboratory computer database. The test results are then electronically recorded on the laboratory computer database and the results are correlated with the previously recorded specimen data. Finally, the recorded and correlated test results data is transmitted to remote locations for reporting.

Preferably, data is gathered at the specimen collection sites by scanning the bar codes on the specimen containers with an electronic recording device having a bar code scanner and then entered into the central computer database by electronically uploading the bar code data and other recorded specimen data from the electronic recording device. This method also preferably includes recording and uploading the electronic signatures of the specimen donors using the electronic recording device. Desirably, the routing and testing step at the automated

reference laboratory also includes verifying the identity and required testing of each specimen prior to testing by interrogating the electronic memory tag on each specimen container for its electronic identity code and comparing the read code with the correlated specimen and prescribed testing requirements in the laboratory computer database. In addition, it may be preferable to transmit the test results data from the laboratory computer database to the associated specimen collection sites by an internet connection. Alternatively, written test result reports may be printed and delivered to remote sites.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood from a reading of the detailed description of the preferred embodiments along with a review of the drawings in which:

FIG. 1 is a front exterior view of a preferred embodiment;

FIG. 2 is a front detail view of the label of the embodiment of FIG. 1;

FIG. 3 is a rear view of the label of FIG.2;

FIG. 4 is a block diagram of an integrated system for managing the collection, control, and testing of diagnostic and/or toxicology specimens and for managing the specimen and testing information associated with such specimens using the apparatus shown in Figures 1-3; and

FIG. 5 is a flow chart showing the flow of information and data about specimen containers, specimens, and specimen tests between the container supplier, the specimen collection site, and the automated laboratory according to the method shown in FIG. 4.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a diagnostic or toxicology specimen container having a wireless electronic memory tag for non-contact storage and retrieval of information. As seen in FIG. 1, a vessel 1 is provided with a cap 2 for sealingly receiving a biomedical

specimen within the vessel 1. An electronic memory tag 3 is affixed to an exterior surface of the vessel 1. An enlarged front view of a preferred embodiment of the electronic memory tag 3 is shown in FIG. 2. The electronic memory tag 3 includes a carrier label 4 which has a front face 5 and a rear face 6. Preferably, the front face 5 is imprinted with an identification bar code 7. A text area 8 is also provided for printing, typing, or writing pertinent information on the front face 5 of the carrier label 4. A detail view of the rear face 6 of the carrier label 4 is shown in FIG.3. An electronic memory device 9 is attached to the rear face 6. Alternatively, the invention may include a separate electronic memory tag 3 and a second printed label having a bar code 7 imprinted thereon (not shown). The apparatus of Figures 1-3 may be used for either a diagnostic or toxicology specimen. For toxicology specimens, the specimen containers may further include a tamper-resistant or tamper-evident locking or sealing device (not shown).

In the preferred embodiment, the electronic memory device 9 is an ultra-thin radio frequency transponder made up of an integrated circuit and an antenna. The transponder has no battery, but is energized when interrogated by radio signals from a reader or scanner. The radio frequency transponder may be configured as a read/write, write-once/read-many, or read-only device as required in a particular embodiment of the invention. Details regarding these transponders and the electronic devices to write information to and read information from such devices are known and need not be shown in the detailed drawings to enable those of ordinary skill in the art to practice the invention. Alternatively, other types of compact, non-contact electronic memory devices may also be used.

A unique electronic identification code for the specimen container is stored on the electronic memory device 9, though the electronic memory device 9 may be selected to be capable of storing any desired information within the memory capacity of the device. For example, Tag-It® brand radio frequency identification systems sold by Texas Instruments,

Inc., of Dallas Texas may be used. Other types of information which may also be stored include identifying and contact information of the supplier of the specimen container, product information about the container, the identity of the collection site using the specimen container, the date and time the specimen container is used to collect a specimen, identifying information about a specimen contained in the container and its donor, and definition of the tests to be performed on the contained specimen. This information may be written to the electronic memory device or read from the device by the specimen container supplier, the specimen collection sites using the containers, or a testing laboratory. In a preferred embodiment, the tag is a read-only tag having only a unique identification code so that the container to which it is affixed can be uniquely identified. That unique identification code may then be correlated with more complete data found on a computer. This simplifies and reduces the cost of the tag.

The present invention also provides an integrated system for managing the collection, control, and testing of diagnostic and/or toxicology specimens and for managing the specimen and testing information associated with such specimens. FIG. 4 shows the sequence of events in the preferred method, and FIG. 5 shows the flow of information and data associated with this method. The process begins by first providing 10 specimen containers having electronic memory tags 3 as shown in Figures 1-3. Preferably, each container has a unique electronic identification code stored on its electronic memory tag 3 and a bar code 7 imprinted on the front face 5 of its carrier label 4. Each electronic identification code and corresponding bar code 7 are correlated 11 and stored 12 on a central computer database 29. The central computer database 29 provides a cross-reference for future identification and control of the specimen containers using either the bar codes 7 or electronic control codes. The specimen containers are then supplied 13 to multiple specimen

collection sites such as hospitals, clinics, and doctors' offices. The bar code is not necessary in all embodiments of the invention.

The provided specimen containers are used to collect 14 biomedical specimens from donors for testing. The specimens may be either diagnostic or toxicology specimens or used in clinical trials. Attendants at the specimen collection site also gather information 14 about each collected specimen, the specimen donor, and the required specimen testing. In this preferred embodiment, the data is collected using an electronic recording device including a bar code scanner for scanning and recording the bar code 7 from each specimen container. Such electronic recording devices are widely known, such as those used in connection with commercial parcel delivery services. One such device 101 is described in U.S. Patent No. 6,094,642 to Stephenson et al., assigned to Federal Express Corporation. Another such device is disclosed in U.S. Patent 5,313,051 to Brigida, et al., assigned to International Business Machines Corp. The specifications of these two patents are hereby incorporated by reference. The attendant's electronic recording device may include a keypad to permit input of information into the system as well as means for uploading data from the electronic recording device to a computer. The electronic identification code stored on the electronic memory tag may be used to identify the specimen container and the specimen contained therein, but the bar code 7 is a preferred method of identification at the specimen collection sites because of the low relative cost of bar code scanners compared to the readers/scanners required to interrogate the electronic memory tags to detect the electronic identification codes. However, the collection sites may alternatively use the electronic memory codes in lieu of the bar codes 7 when an electronic reader/scanner is available. In addition, collection sites having the capability may electronically write the gathered specimen information to the electronic memory tag on the specimen container holding the associated specimen. For toxicology specimens, the gathered data includes the electronic authorization and

identification signatures of the specimen donors. Preferably, the data input software prevents unauthorized tampering with the input data once the signature has been received to enable a reliable chain of custody record to be established.

Next, the gathered identification and specimen data is entered 15 into the central computer database 29 by uploading the data from the electronic recording device or by manual entry. The uploaded data is then correlated 16 with the previously stored specimen container identification data in the central computer database 29.

The correlated data 30 is then transmitted 17 to a laboratory computer database 33 such as by an internet connection. Other connections such as LAN, WAN, dial-up modems or the like can be substituted and, as used herein for internet connections should be construed to include such connections. This data 30 may be used by the laboratory to define 18 a queue of specimens awaiting collection and delivery to the laboratory from the multiple collection sites. The laboratory or other actor then defines 18 a route and schedule 34 for the efficient and timely gathering of specimens from the multiple collection sites and delivery to the laboratory . The specimens are then gathered 19 according to the route and schedule 34 by one or more couriers and delivered 20 to the laboratory.

The delivered specimens are interrogated 21 at the laboratory using an electronic reader/scanner to detect the electronic identification codes stored on the electronic memory tags 3. The specimen containers can be remotely scanned in mass at a receiving station with an electronic reader or scanner, even while still inside their protective shipping cartons or containers, thereby reducing the elapsed time and labor cost associated with identifying and receiving each specimen individually. The data 31 detected from the specimens is input into the laboratory computer database 33 and correlated 22 with the other corresponding specimen data in the laboratory computer database 33. The correlated data is used 23 by a

microprocessor controlling the automated laboratory equipment to sort the specimens and schedule the prescribed diagnostic or toxicology tests for each specimen.

For some types of tests, particularly toxicology tests, human inspection of the specimen container is desirable at the laboratory, and the present invention aids this process. As a series of containers pass the inspector, he or she may inspect and input by a simple keystroke or other motion his or her indication that the container is intact and of acceptable quality for the prescribed test. The inspector making such judgment may automatically identify a specimen by scanning its bar code 7 or electronically reading its tag 3.

The sorted and scheduled specimens are then routed through conventional automated handling and testing equipment and tested 24. Test results 32 are electronically recorded 25 and entered into the laboratory database 33. The test results are correlated 25 with the previously stored specimen data 31 and electronic test results reports 35 are transmitted 26 to remote locations via internet connections. Alternatively, written test results reports 36 may be generated and sent to the remote locations.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications and combinations of the illustrative embodiments, as well as other embodiments of the invention, will be apparent to persons skilled in the art upon reference to the description. It is therefore intended that the appended claims encompass any such modifications or embodiments.

What is claimed is:

1. A diagnostic specimen container comprising a biomedical specimen collection vessel and a wireless electronic memory tag for non-contact storage and retrieval of information.

2. A diagnostic specimen container as claimed in claim 1 wherein the electronic memory tag includes a radio frequency transponder.

3. A diagnostic specimen container as claimed in claim 1 wherein the electronic memory tag contains stored data including an identification code for the container.

4. A diagnostic specimen container as claimed in claim 3 further including a label imprinted with an identifying bar code.

5. A diagnostic specimen container as claimed in claim 1 wherein the electronic memory tag contains stored data including the identity of the supplier of the container and product information about the container.

6. A diagnostic specimen container as claimed in claim 1 wherein the electronic memory tag contains stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

7. A diagnostic specimen container as claimed in claim 6 wherein the electronic memory tag contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

8. A diagnostic specimen container comprising:

a collection vessel and a wireless electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information;

data stored on the electronic memory tag including an identification code for the container, the identity of the supplier of the container and product information about the container, identifying information about a specimen contained in the vessel and about the specimen donor, and definition of the analytical tests to be performed on the specimen in the vessel; and

a label imprinted with an identifying bar code.

9. A toxicology specimen container comprising a collection vessel configured to receive and contain a toxicology specimen and a wireless electronic memory tag for non-contact storage and retrieval of information.

10. A toxicology specimen container as claimed in claim 9 wherein the electronic memory tag includes a radio frequency transponder.

11. A toxicology specimen container as claimed in claim 9 wherein the electronic memory tag contains stored data including an identification code for the container.

12. A toxicology specimen container as claimed in claim 11 further including a label imprinted with an identifying bar code.

13. A toxicology specimen container as claimed in claim 9 wherein the electronic memory tag contains stored data including the identity of the supplier of the container and product information about the container.

14. A toxicology specimen container as claimed in claim 9 wherein the electronic memory tag contains stored data including identifying information about a specimen contained in the vessel and about the specimen donor.

15. A toxicology specimen container as claimed in claim 14 wherein the electronic memory tag contains stored data further including definition of the analytical tests to be performed on the specimen in the vessel.

16. A toxicology specimen container as claimed in claim 9 wherein the electronic memory tag contains stored data including an encoded electronic signature of the donor of a toxicology specimen.

17. A toxicology specimen container comprising:

a biomedical specimen collection vessel and a wireless electronic memory tag including a radio frequency transponder for non-contact storage and retrieval of information;

data stored on the electronic memory tag including an identification code for the container, the identity of the supplier of the container and product information about the container, identifying information about a specimen contained in the vessel and about the specimen donor, definition of the analytical tests to be performed on the specimen in the vessel, and an encoded electronic signature of the donor of the toxicology specimen in the vessel; and

a label imprinted with an identifying bar code.

18. A method for electronically storing information on a diagnostic or toxicology specimen container and remotely reading information from the container comprising:

providing a biomedical specimen container having a wireless electronic memory tag;

electronically storing data on the electronic memory tag; and

reading the stored information from the electronic memory tag with a non-contact electronic reader or scanner.

19. A method for recording information about a diagnostic or toxicology specimen on a diagnostic or toxicology specimen container comprising:

providing a biomedical specimen container having a wireless electronic memory tag;

collecting a specimen from a donor in the specimen container; and

electronically storing information about the specimen, donor, and/or tests to be performed on the specimen on the electronic memory tag.

20. A method as claimed in claim 19 further including collecting and storing the electronic signature of the specimen donor on the electronic memory tag.

21. A method as claimed in claim 19 further including storing the results of the analytical tests performed on the specimen in the container on the electronic memory tag.

22. A method for managing the gathering of diagnostic and/or toxicology specimens from multiple specimen collection sites and the delivery of the collected specimens to a reference laboratory comprising:

collecting identity and test data for specimens and specimen donors at multiple collection sites;

entering the collected data into collection site computer databases;

transmitting the collected data from the collection site computer databases to a computer at a reference laboratory by internet connections;

compiling and processing the transmitted data with the laboratory computer to generate a schedule and route for gathering the specimens from the specimen collection sites; and

gathering the specimens from the specimen collection sites according to the schedule and route and delivering the specimens to the reference laboratory.

23. A method as claimed in claim 22 wherein data collection includes reading information from electronic memory tags attached to containers containing the specimens by scanning the electronic memory tags with an electronic reader/scanner.

24. A method as claimed in claim 22 wherein data collection includes scanning bar codes imprinted on labels on the specimen containers.

25. A method as claimed in claim 22 wherein data collection includes entering data into a portable electronic recording device and data entry includes uploading the recorded information from the electronic recording device into a local computer at each specimen collection site.

26. A method as claimed in claim 22 wherein data collection includes collecting the electronic signatures of specimen donors and data entry includes entering the electronic signatures of the specimen donors into the local computer database.

27. A method for controlling the receipt, routing, and testing of diagnostic or toxicology specimens at an automated reference laboratory comprising:

delivering diagnostic and/or toxicology specimens to the automated reference laboratory which are contained in specimen containers having specimen and testing information stored on radio frequency memory tags affixed to the specimen containers;

scanning and reading the specimen and testing information from the electronic memory tags on the specimen containers with electronic scanners or readers and transmitting the information to a microprocessor for controlling the automated laboratory equipment; and

processing the read information with the microprocessor and using the processed information to control the sorting, routing, and analytical testing of the specimens by the automated laboratory equipment.

28. A method as claimed in claim 27 further including electronically writing the results of the analytical test or tests for each analyzed specimen to the electronic memory tag on the specimen container containing the corresponding analyzed specimen.

29. A method as claimed in claim 27 further including electronically storing the results of the analytical test or tests and the corresponding specimen identification data on a laboratory computer database.

30. A method as claimed in claim 29 further including printing the analytical test results and corresponding specimen identification data stored on the laboratory computer database to a written test results report.

31. A method as claimed in claim 29 further including transmitting the analytical test results data and corresponding specimen identification data stored on the laboratory computer database to the corresponding original specimen collection site by an internet connection.

32. A method for managing the collection, control, and testing of diagnostic and/or toxicology specimens and for managing the specimen and testing information associated with such specimens comprising:

providing encoded specimen containers having electronic memory tags with electronic specimen identification codes stored therein and having bar code labels imprinted with identifying bar codes;

correlating the electronic specimen identification code and identifying bar code for each encoded specimen container and storing the correlated codes on a central computer database;

supplying the encoded specimen containers to multiple specimen collection sites;

collecting specimens from specimen donors and placing the specimens in the encoded specimen containers at the specimen collection sites;

gathering data about the collected specimens, specimen donors, and prescribed specimen tests at the specimen collection sites, correlating the gathered data with the identifying bar codes on the corresponding specimen containers, and entering the gathered and correlated data into the central computer database;

transmitting the gathered and stored specimen, donor, and testing data and correlated identity codes from the central computer database to a laboratory computer database at an automated reference laboratory by an internet connection;

processing the received data at the reference laboratory and defining a queue of specimens awaiting collection for delivery to the automated reference laboratory;

using the queue to define a schedule and route for collecting the specimens from the specimen collection sites for delivery to the automated reference laboratory;

gathering the specimens from the specimen collection sites according to the schedule and route and delivering the collected specimens to the automated reference laboratory;

electronically interrogating the electronic memory tags on the delivered specimen containers to detect the associated electronic identity codes and correlating the read data with the specimen data previously transmitted to the laboratory computer database;

automatically sorting the specimens for testing and establishing testing schedules using the correlated specimen and testing data in the laboratory computer database;

automatically routing and testing the specimens through the automated reference laboratory using the correlated specimen and testing data in the laboratory computer database;

electronically recording the test results on the laboratory computer database and correlating the results with the previously recorded specimen data; and

transmitting the recorded and correlated test result data to remote locations.

33. A method as claimed in claim 32 wherein the data gathering at the specimen collection sites includes scanning the bar codes on the specimen containers with an electronic recording device having a bar code scanner and data entry at the specimen collection sites

includes electronically uploading the bar code data and other recorded specimen data from the electronic recording device to the central computer database.

34. A method as claimed in claim 33 further including recording and uploading electronic signatures of the specimen donors using the electronic recording device.

35. A method as claimed in claim 32 wherein the routing and testing step at the automated reference laboratory includes the step of verifying the identity and required testing of each specimen prior to testing by interrogating the electronic memory tag on each specimen container for its electronic identity code and comparing the read code with the correlated specimen and prescribed testing requirements in the laboratory computer database.

36. A method as claimed in claim 32 wherein the transmission includes transmitting the test results data from the laboratory computer database to the associated specimen collection sites by an internet connection.

37. A method as claimed in claim 32 further including printing written test result reports and delivering the written test result reports to remote sites.

ABSTRACT

A paperless system for identifying and controlling biomedical specimens and managing essential information associated with such specimens. The invention provides a diagnostic or toxicology specimen container having an electronic memory tag for remote non-contact recording and reading of data stored therein. The invention also provides improved methods for controlling the identity of such specimens, coordinating the relay of such specimens between remote specimen collection sites and reference laboratories, and managing essential information associated with such specimens by using the electronic memory tags.

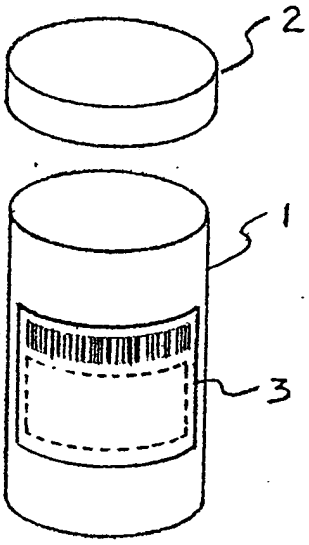


FIG. 1

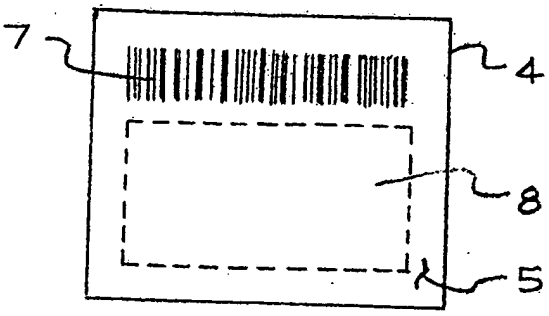


FIG. 2

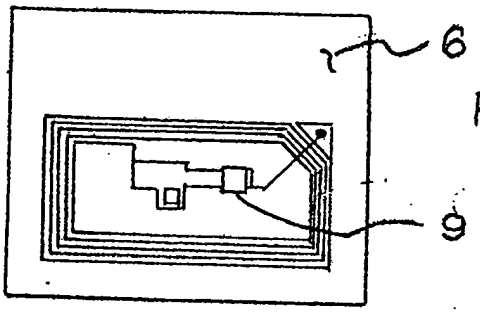
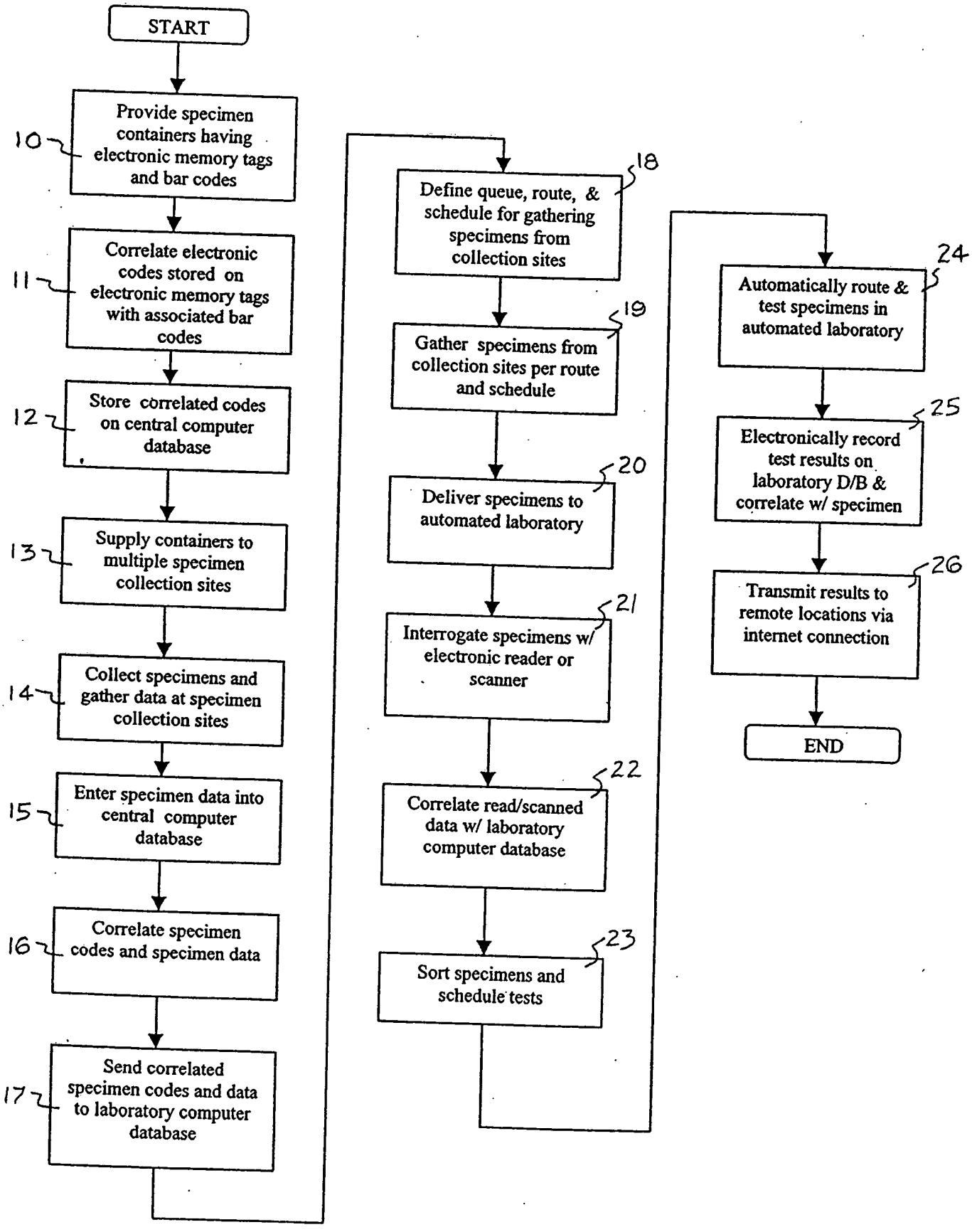


FIG. 3

FIG. 4


START
Provide specimen containers having electronic memory tags and bar codes
10
Correlate electronic codes stored on electronic memory tags with associated bar codes
11
Store correlated codes on central computer database
12
Supply containers to multiple specimen collection sites
13
Collect specimens and gather data at specimen collection sites
14
Enter specimen data into central computer database
15
Correlate specimen codes and specimen data
16
Send correlated specimen codes and data to laboratory computer database
17
Define queue, route, & schedule for gathering specimens from collection sites
18
Gather specimens from collection sites per route and schedule
19
Deliver specimens to automated laboratory
20
Interrogate specimens w/ electronic reader or scanner
21
Correlate read/scanned data w/ laboratory computer database
22
Sort specimens and schedule tests
23
Automatically route & test specimens in automated laboratory
24
Electronically record test results on laboratory D/B & correlate w/ specimen
25
Transmit results to remote locations via internet connection
26
END

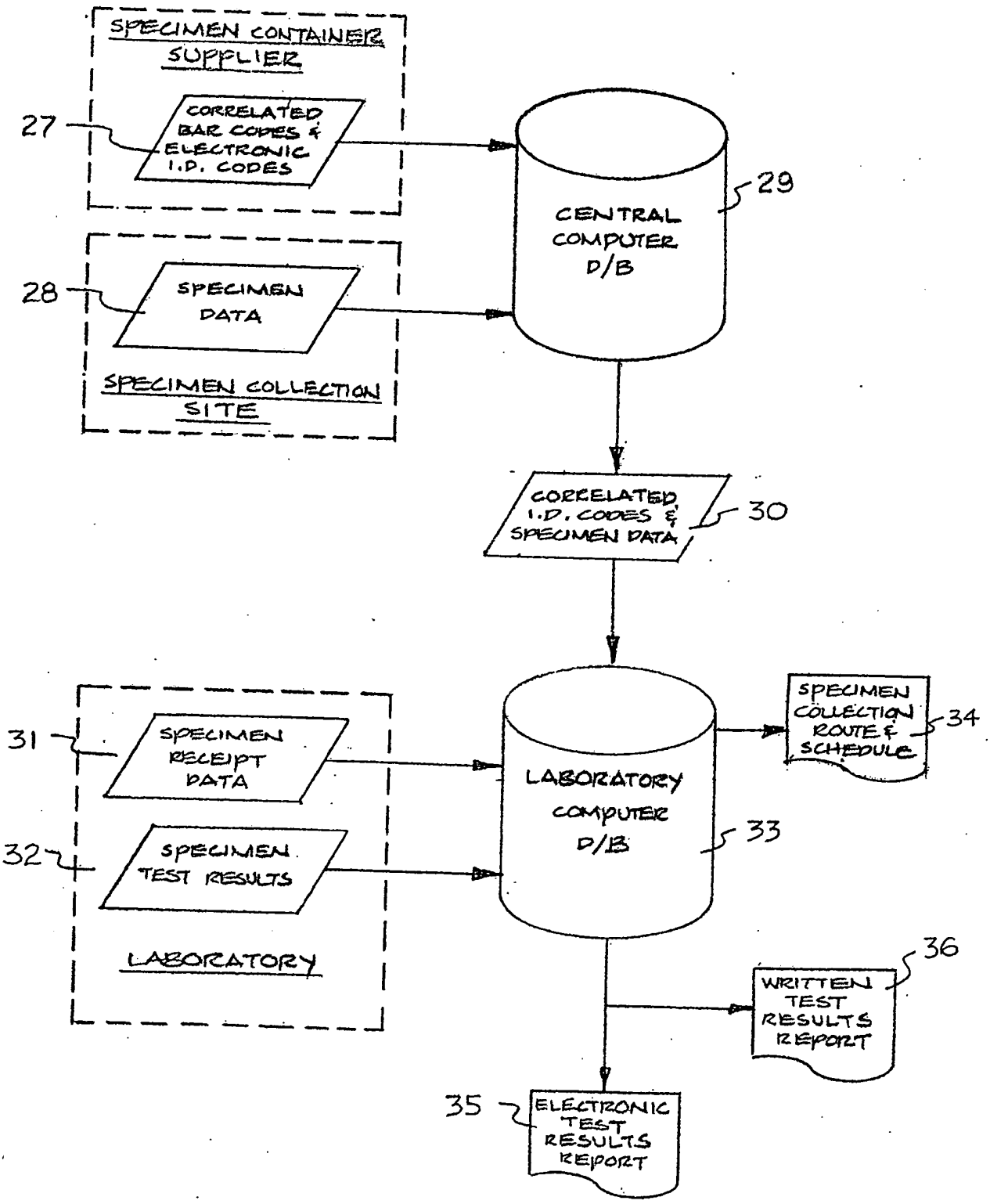

SPECIMEN CONTAINER SUPPLIER
27
CORRELATED BAR CODES & ELECTRONIC I.D. CODES
28
SPECIMEN DATA
SPECIMEN COLLECTION SITE
CENTRAL COMPUTER D/B
29
CORRELATED I.D. CODES & SPECIMEN DATA
30
31
SPECIMEN RECEIPT DATA
32
SPECIMEN TEST RESULTS
LABORATORY
LABORATORY COMPUTER D/B
33
SPECIMEN COLLECTION ROUTE & SCHEDULE
34
WRITTEN TEST RESULTS REPORT
36
35
ELECTRONIC TEST RESULTS REPORT

FIG. 5

RULE 63 (37 C.F.R. 1.63)
DECLARATION FOR PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES the specification of which (check applicable box(es)):

☒ is attached hereto.
☐ was filed on as U.S. Application Serial No.
☐ was filed as PCT international application No. PCT/ / on and (if applicable to U.S. or PCT application) was amended on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 C.F.R. 1.56(a). I hereby claim foreign priority benefits under 35 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed or, if no priority is claimed, before the filing date of this application:

Prior Foreign Application(s): Application Number	**Country**	**Day/Month/Year Filed**

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application listed below:

Prior Provisional Application(s): Application Serial No.	**Day/Month/Year Filed**

I hereby claim the benefit under 35 U.S.C. 120/365 of all prior United States and PCT international applications listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. 1.56(a) which occurred between the filing date of the prior applications and the national or PCT international filing date of this application:

Prior U.S./PCT Application(s): Application Serial No.	**Date/Month/Year Filed**	**Status: patented, pending, abandoned**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1) Inventor's Signature X _____ Date X _____
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Residence (City) Greensboro State/Foreign Country) NC
Post Office Address 3901 Gaston Road Zip Code 27407

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Residence (City) Greensboro State/Foreign Country) NC
Post Office Address 6202 Clarkwood Circle Zip Code 27410

3) Inventor's Signature X _____ Date X _____
Inventor's Name (typed) Mike (First) Lewis (Family Name) USA (Citizenship)
Residence (City) Greensboro State/Foreign Country) NC
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FOR ADDITIONAL INVENTORS, check box ☒ and attach sheet with same information and signature and date for each.

Rhodes & Mason (4/98)

28106

RULE 63 (37 C.F.R. 1.63)
DECLARATION FOR PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled PAPERLESS CHAIN OF CUSTODY EVIDENCE FOR LAB SAMPLES the specification of which (check applicable box(es)):

☒ is attached hereto.
☐ was filed on as U.S. Application Serial No.
☐ was filed as PCT international application No. PCT/ / on and (if applicable to U.S. or PCT application) was amended on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 C.F.R. 1.56(a). I hereby claim foreign priority benefits under 35 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed or, if no priority is claimed, before the filing date of this application:

Prior Foreign Application(s): Application Number	**Country**	**Day/Month/Year Filed**

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application listed below:

Prior Provisional Application(s): Application Serial No.	**Day/Month/Year Filed**

I hereby claim the benefit under 35 U.S.C. 120/365 of all prior United States and PCT international applications listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. 1.56(a) which occurred between the filing date of the prior applications and the national or PCT international filing date of this application:

Prior U.S./PCT Application(s): Application Serial No.	**Date/Month/Year Filed**	**Status: patented, pending, abandoned**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

4) Inventor's Signature X _____ Date X _____
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Residence (City) _____ (State/Foreign Country) _____
Post Office Address _____ Zip Code _____

6) Inventor's Signature _____ Date _____
Inventor's Name (typed) _____ (First) _____ (Middle Initial) _____ (Family Name) _____ (Citizenship)
Residence (City) _____ (State/Foreign Country) _____
Post Office Address _____ Zip Code _____

FOR ADDITIONAL INVENTORS, check box ☒ and attach sheet with same information and signature and date for each.

Rhodes & Mason (4/98)

28106

DERWENT-ACC-NO: 1999-311370
DERWENT-WEEK: 199926

TITLE: Method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) - by applying an electronic identification tag to each container as it passed through the system

PATENT-ASSIGNEE: ANONYMOUS[ANON]

PRIORITY-DATA: 1999RD-0421048 (April 20, 1999)

PATENT-FAMILY:

PUB-NO	PUB-DATE	LANGUAGE	PAGES	MAIN-IPC
RD 421048 A	May 10, 1999	N/A	000	B01J 000/00

APPLICATION-DATA:

PUB-NO	APPL-DESCRIPTOR	APPL-NO	APPL-DATE
RD 421048A	N/A	1999RD-0421048	April 20, 1999

INT-CL (IPC): B01J000/00

ABSTRACTED-PUB-NO: RD 421048A

BASIC-ABSTRACT: This development incorporates electronic identification tags on each chemical container. The identification (II) tags could be self-powered or passive transponder type. Electro-optical techniques, "Button Memory" (direct contact reader powered memory), and Radio Frequency Identification, a non-contact reader powered memory), and Radio Frequency Identification, a non-contact reader powered memory, are some of the methods that can be used. The ID tag with each container individualises the solvents, reagents, intermediates and finished compounds within the CSS. The ID tag can be applied to the container in several ways. It can be placed in the container with the chemical, or mechanically attached to the container, or be an integral part of the container. The tag can be read at a reader station located within the CSS. Another method would incorporate the reader into the robotic arm that, from time to time, would transport the chemical container from point to point in the CSS. ID tags with a Read Only Memory (ROM) provide only a serial number; Write Once Read Many (WORM) allows data to be written a single time to a fixed memory size; Read/Write (R/W) memory is the most capable as it allows data to be written, erased, and rewritten.

USE - Tracking compounds within chemical synthesis systems.

ADVANTAGE - ID tags can store much more information than bar codes. ID tag

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 004 359 A2

(12) EUROPEAN PATENT APPLICATION

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(54) Partitioned specimen label for collection containers

(57) A substrate removably attached to a container that can be linked electronically to the operating stations in a laboratory and/or removed and subsequently attached to a document or another container. More particularly, the substrate is a partitioned label with human readable information and electronically readable information.

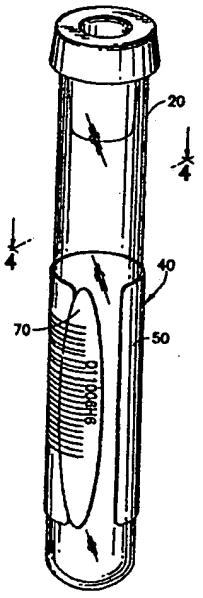

FIG.1

EP 1 004 359 A2

Description

BACKGROUND OF THE INVENTION

1. Field of Invention

[0001] This invention relates to containers or vessels for collecting fluid samples from patients, that comprise means for containing and sharing information about the contents of the fluid samples in the container and the patient. More particularly, this invention relates to a means that is removably affixed to a vessel or container that can be linked electronically to the operating stations in a laboratory and/or removed mechanically and subsequently attached to another document or container.

2. Description of Related Art

[0002] Test specimens are typically collected by a medical technician, preferably at a medical facility, for testing in a container. Specimens, such as blood, are placed in containers called blood collection tubes and transported or shipped to a test facility together with test request documents.

[0003] It is important that once the specimen is collected in a container, that the donor of the specimen is properly identified. Incorrect identification could result in various misdiagnosis. Any indication that the specimen is not properly identified would require recollection. The test facility matches the blood collection tubes and test request documents received from the medical facility, performs the prescribed tests indicated by the test request document on the specimens and reports the test results to the medical facility.

[0004] Often, a physician may request multiple tests for one patient. Therefore, tests carried out by a test facility involve several thousand items, and the sizes and shapes of the containers that hold the specimens also include several dozen types. Therefore, laboratory facilities can be faced with managing thousands of requests per day. This presents many challenges in assuring that results are accurately transcribed back to the requesting physician and then ultimately to the patient.

[0005] In current laboratory settings, there are several ways that a container containing a specimen can arrive in a laboratory. For example, a container is transported from the collection site with a separate document such as a test request to the testing facility. The personnel at the testing facility receive these separate items and begin processing them together. This can involve entering data from the test request into a computer that electronically links test request information to information about the patient that is already available in the computer system. Additional steps may include obtaining some type of label and attaching it to the container.

[0006] These processing steps are subject to human error which could result with inaccurate information and tests results. Therefore, a need exists to link patient, test specimen and test request information that is efficient, cost effective, will enhance the accuracy of reporting test results and will eliminate the need for secondary labeling of containers.

[0007] Currently, collection containers are over-labeled with an identifier to control and monitor the specimens prior to and during processing. In most cases, and for those laboratories using integrated, automated systems for specimen processing, the identifier is a barcode.

[0008] There exists a need to improve the efficiency of systems for specimen processing whereby information can be easily found on the collection container.

SUMMARY OF THE INVENTION

[0009] The present invention is a means for providing electronic information onto or into substrates that can be placed onto, uncoded or embedded with a container prior to the container being used as a specimen collection device.

[0010] Preferably, the substrate may contain human readable information from the label or the collection vessel.

[0011] Preferably, the substrate may contain electronic information technology that can be activated, scanned, transferred and stored into other media.

[0012] Most preferably, the substrate includes a means for detaching a portion of the substrate for use with related documents or other related containers.

[0013] The present invention is a collection container comprising a label that comprises a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms.

[0014] Preferably, the label of the present invention comprises a permanent section and a peel away section. Most preferably, a double bar code is on the label wherein the permanent section and the peel away section of the label share the barcode information and features. In addition to the barcode information on the label, the label may also contain a writing area and/or be color coordinated with other information such as the type of container it is associated with.

[0015] Preferably, the bar code information contains information regarding the tube, the test requirements to be performed and/or patient identification.

[0016] Most preferably, the peel away section comprises a tab that allows the user to quickly and efficiently remove the peel away section from the label and attach it to a document or another container.

[0017] Most preferably, the size of the double bar code is such that it can surround the container with a

wrap angle of up to about 360°. Therefore, misreading of the bar code by electronic devices is substantially minimized because alignment of the electronic device or scanner and label is not required. The bar code angle wrap provides an improved interface with both manual and automatic bar code scanning devices. In the testing laboratory, some automation tube handling systems will transport the tubes on a track to various testing stations in the laboratory environment. The tube, with a bar code label and a small angle wrap, is rotated while scanned to ensure high quality bar code reads at various points along the track. Therefore, the bar code label with a wide angle wrap minimizes the rotation necessary to read the bar code, thereby increasing the production rate of the testing stations in the laboratory.

[0018] Preferably, a bar code wrap angle of 360° will provide a means for the automated equipment to read the bar code with minimal rotation and less time.

[0019] In use, the label is on a container that is subsequently used in a specimen collection procedure. The barcode on the label contains human readable information and/or electronic information that can be activated, scanned, transferred and stored into other media. Once a specimen is collected, the peel away section of the label is removed and applied to a test request form.

[0020] The label of the present invention minimizes the amount of curl-up associated with the inherent material characteristics of pulling and peeling action.

[0021] Most notably, the double barcode label of the present invention allows the customer to create a direct link between the patient form, patient and specimen/tube.

DESCRIPTION OF THE DRAWINGS

[0022]

FIG. 1 is a perspective view of a tube with the label of the present invention.

FIG. 2 is a perspective view of the label of the present invention of FIG. 1.

FIG. 3 is a perspective view of the bottom or underside of the label of the present invention of FIG. 1.

FIG. 4 is a cross-sectional view of the tube with the label of FIG. 1 taken along 4-4 thereof.

FIG. 5 illustrates the user peeling a portion of the label from the tube.

FIG. 6 illustrates the side peel being affixed to a client document.

FIG. 7 is an alternate embodiment of the invention.

FIG. 8 illustrates a flow chart according to the method of using the label system of the present invention.

DETAILED DESCRIPTION

[0023] While this invention is satisfied by embodiments in many different forms, there is shown in the drawings and will herein be described in detail, the preferred embodiments of the invention, with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to limit the invention to the embodiments illustrated. Various other modifications will be apparent to and readily made by those skilled in the art without departing from the scope and spirit of the invention. The scope of the invention will be measured by the appended claims and their equivalents.

[0024] FIG. 1 illustrates a sample collection tube **20** and a label **40**. Label **40** comprises a permanent portion **50** and a peel away portion **70**.

[0025] As shown in FIGS. 1, 2 and 3, permanent portion **50** comprises a first side **52**, a second side **54**, a third side **56**, a fourth side **58**, a bottom side or an underside **60** and a top side **62**. First side **52** is across from second side **54** and third side **56** is across from fourth side **58**. Although it is within the purview of the invention that fourth side **58** may be a geometric shape, for purposes of illustration an elliptical shape is shown in FIGS. 2 and 3. In addition, bottom side **60** includes an adhesive **98** for attaching the label to a container.

[0026] As shown in FIGS. 1, 2 and 3, peel away portion **70** includes a first side **72**, a second side **74**, and a third side **76**, a fourth side **78**, a bottom side **80** and a top side **82**. Peel away portion **70** further includes a dead-ended lift tab **84** comprising a non-stick portion **96** so that the peel away portion may be easily grasped and removal from the container is facilitated. The non-stick portion is located on bottom side **80** near fourth side **78**. The remaining area of bottom side **80** includes an adhesive **98** for attaching the label to a container or a document. Although it is within the purview of the invention that peel away portion **70** may be a geometric shape for purposes of illustration an elliptical shape is shown in FIGS. 1, 2 and 3.

[0027] Peel away portion **70** and permanent portion **50** are joined by a perforation **94** at fourth side **58** of the permanent portion and third side **76** of the elliptical portion.

[0028] The label further includes a tandem double barcode **90** located on top side **62** of permanent portion **50** and extending onto top side **82** of the peel away portion **70**. The double barcode design is of a size so that it extends approximately 180° or more around the container.

[0029] As shown in FIG. 2, the same or tandem digit and/or alphanumeric combination **89** is located on the peel away section and the permanent section of the label. The first two of the digits are fixed and identify the

tube and product type for features such as but not limited to tube size, tube material and internal additives. These first two digits allow automatic laboratory systems to recognize what type of collection vessel it is handling to facilitate more efficient processing of handling operations. The remaining alphanumeric elements can range in number but are preferred to be five or six digits and are most preferably six digits that are a base thirty-one alphanumeric unique identifier. The advantage of such a ten-digit bar code is that some of the digits can be used to identify the manufacturing location.

[0030] Most preferably, label **40** is applied to a container by an automated manufacturing process so that the label is pre-attached to the container prior to being used by a medical facility and/or prior to being transported to a testing facility.

[0031] Most preferably, perforation **94** is a micro-perforation wherein the user initiates the removal of the peel away portion.

[0032] In use, as shown in FIG. 4, the label is attached to a tube. As shown in FIG. 5 the user grips lift tab **84** of peel away portion **70** and peels and pulls the portion towards the user whereby peel away portion **70** is detached from the permanent portion of the label. The user then affixes the peel away portion to a test request form as shown on FIG. 6 or to another container or item as may be required.

[0033] The lift tab is easily grasped and facilitates removal of the peel away portion from a container. The lift tab is particularly advantageous to users in medical or test facilities who wear protective gloves.

[0034] The peeling and pulling load of the elliptical shape of the peel away portion assists in distributing the load over a large area as compared to a traditional straight line perforation. Distributing the peeling and pulling load across an elliptical shape substantially prevents curl-up of the peel away portion. Curl-up of the peel away portion could prevent the user from using the portion or affixing it to the client order or test request form and it also reduces the necessary force to remove it.

[0035] The elliptical micro-perforation also prevents tear away from the perforation line that occurs when the adhesive forces exceed the label tear strength which in turn renders information on the label non-readable.

[0036] The elliptical lift tab avoids wrinkled corners as may be present on right angled labels and it eases placement of the tube into test tube racks without the label getting caught on the rack.

[0037] Although the peel away portion of the label in accordance with the present invention is an elliptical shape, it is within the purview of this invention that any shape that permits the distribution of the peeling and pulling load so that curl-up or tearing is minimized may be well suited to be used in the present invention.

[0038] Although the container in accordance with the present invention may be a sample collection tube or a culture bottle, other containers may be well suited to be used with the label of the present invention.

[0039] The alternate embodiment as shown in FIG. 7 includes many components which are substantially identical to the components of FIGS. 2 and 3. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 2 and 3, except that a suffix "a" will be used to identify those similar components in FIG. 7.

[0040] The alternate embodiment of the label of the present invention is illustrated in FIG. 7. As shown in FIG. 7, the label contains a second peel away portion **120**.

[0041] As shown in FIG. 8, the system and method for using the label of the present invention is illustrated. As depicted in **150** in the box diagram of FIG. 8, label **40** is applied to a tube. A sample is then drawn from a patient into the tube with the label as depicted in **160** in the box diagram of FIG. 8. As shown in alternative steps **180, 190** and **200**, peel away portion **70** of the label may be applied to a test request form, may be left on the tube or applied to a secondary tube. As shown in step **220**, tests are then performed on the patient's sample and the label and tube information is electronically read. As shown in step **230**, the test results are then reported.

Claims

1. A collection container comprising a label comprising a permanent section, a peel away section, a machine readable double bar code identification wherein the permanent section and the peel away section share said bar code identification.

2. The collection container of Claim 1, wherein said label further comprises a tab on said peel away section whereby said tab allows the user to quickly and efficiently remove said peel away section.

3. The collection container of Claim 1, wherein said peel away section is removed and applied to a test request form.

4. The collection container of Claim 4, wherein said peel away section is an elliptical shape.

5. The collection container of Claim 1, wherein said peel away portion and said permanent portion are removably joined by a perforation.

6. The collection container of Claim 1, wherein said machine's readable double bar code identification is a tandem double barcode.

7. The collection container of Claim 1, wherein said label further comprises the same digit and/or alphanumeric combination on said peel away portion and said permanent portion.

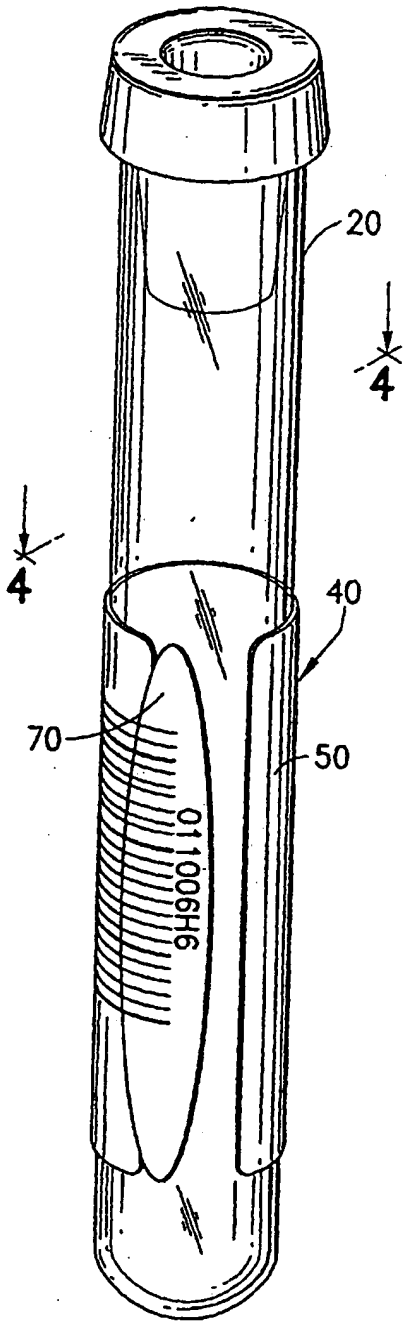

FIG.1

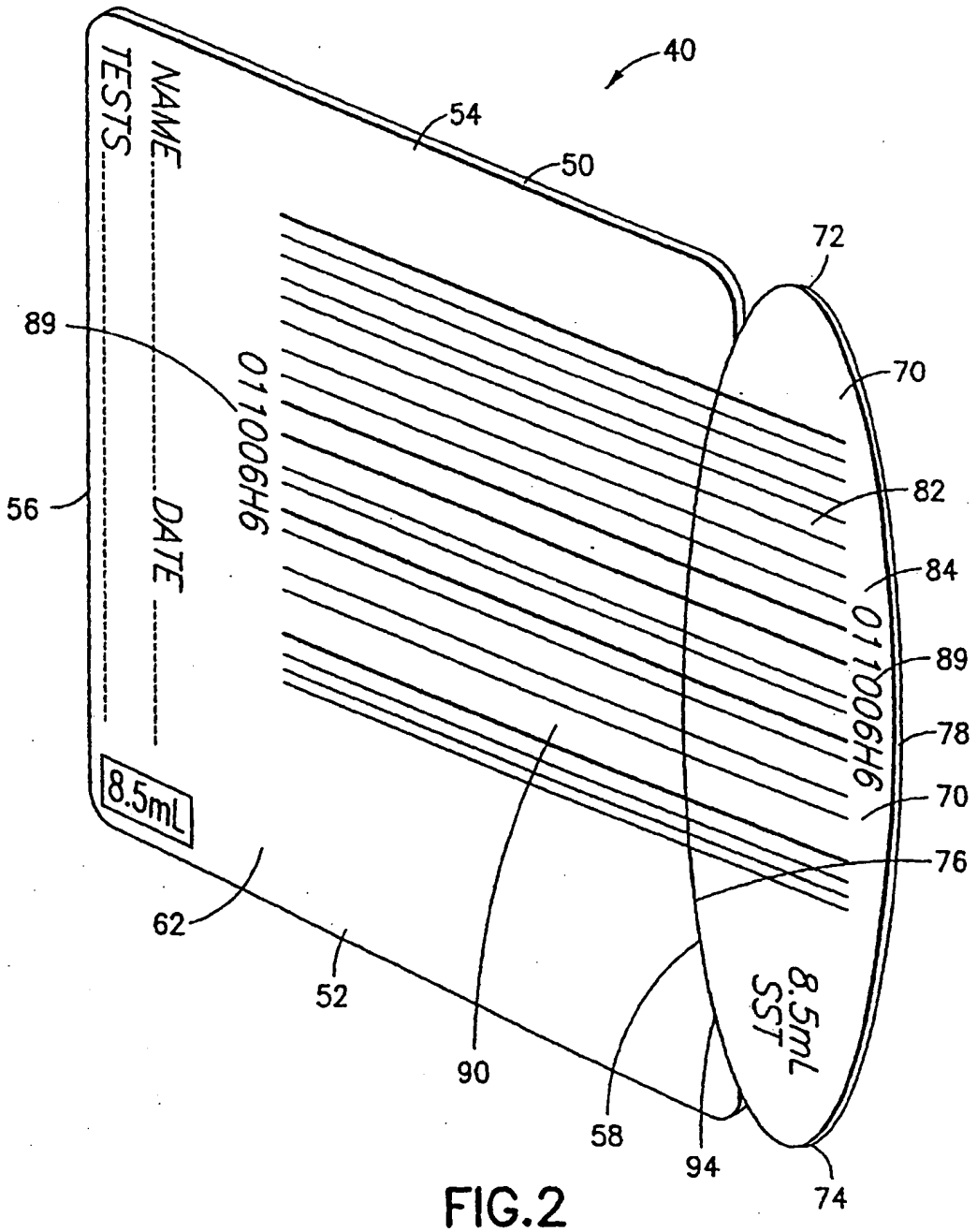
40
54
50
72
89
70
82
84
89
78
70
76
56
62
52
90
58
94
74
NAME
TESTS
DATE
01100GH6
8.5mL
01100GH6
8.5mL
SST

FIG.2

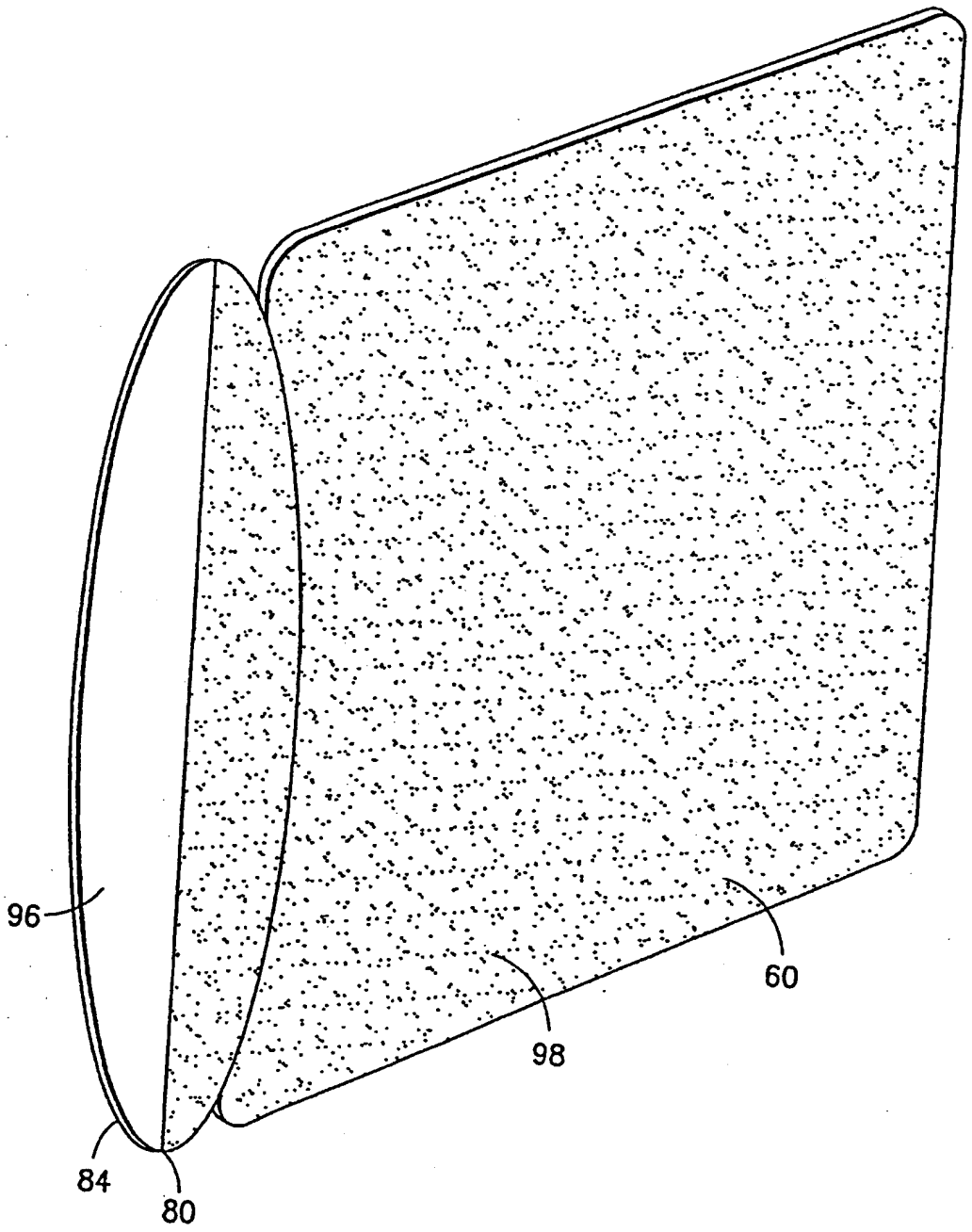

FIG.3

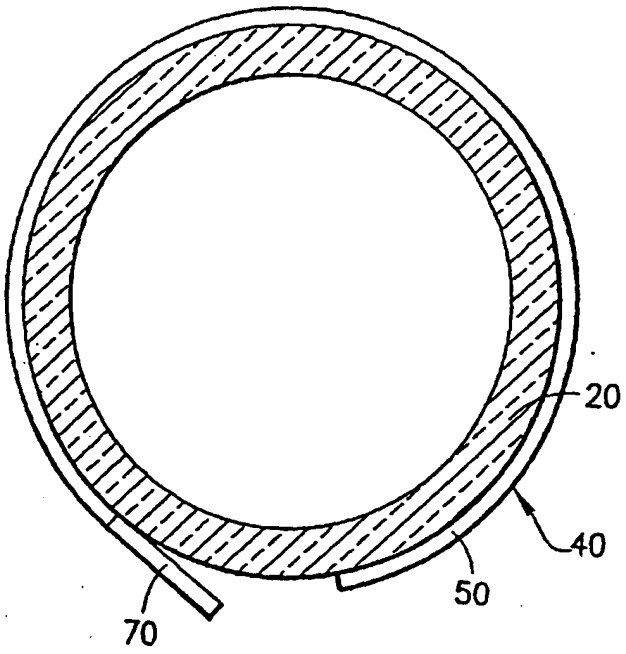

FIG.4

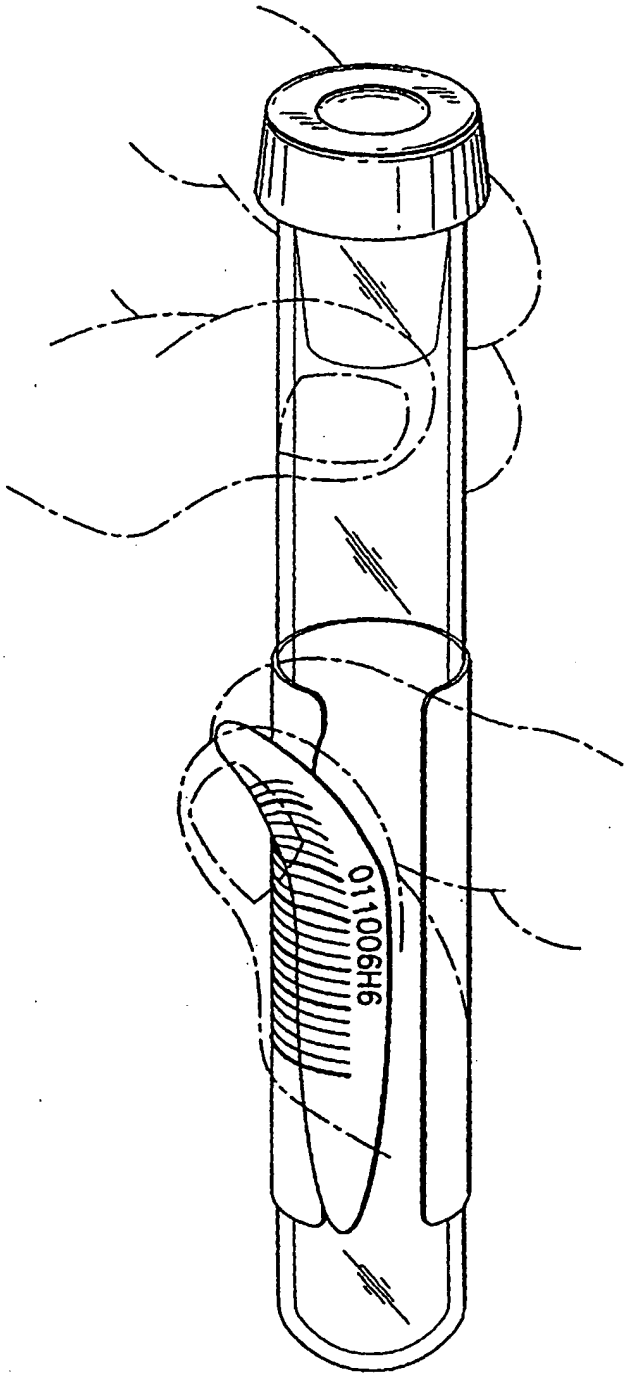

FIG.5

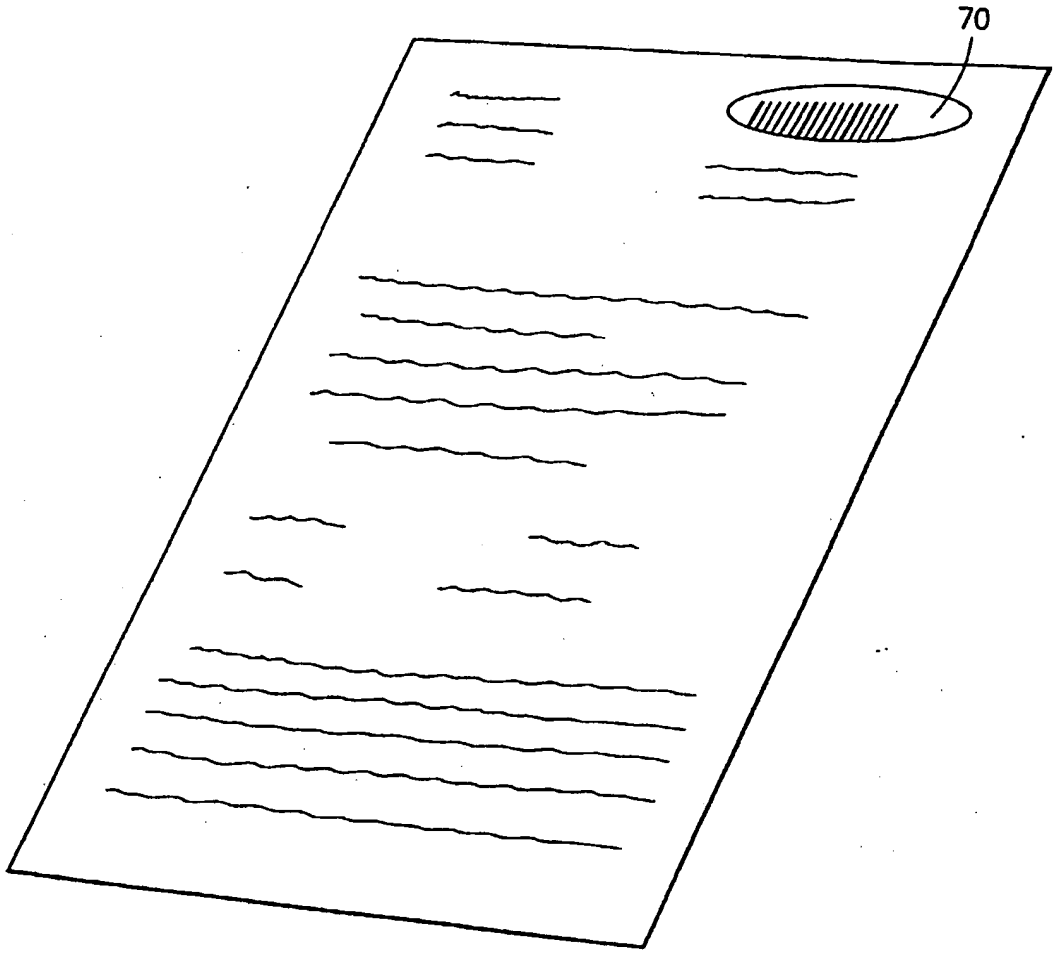

FIG.6

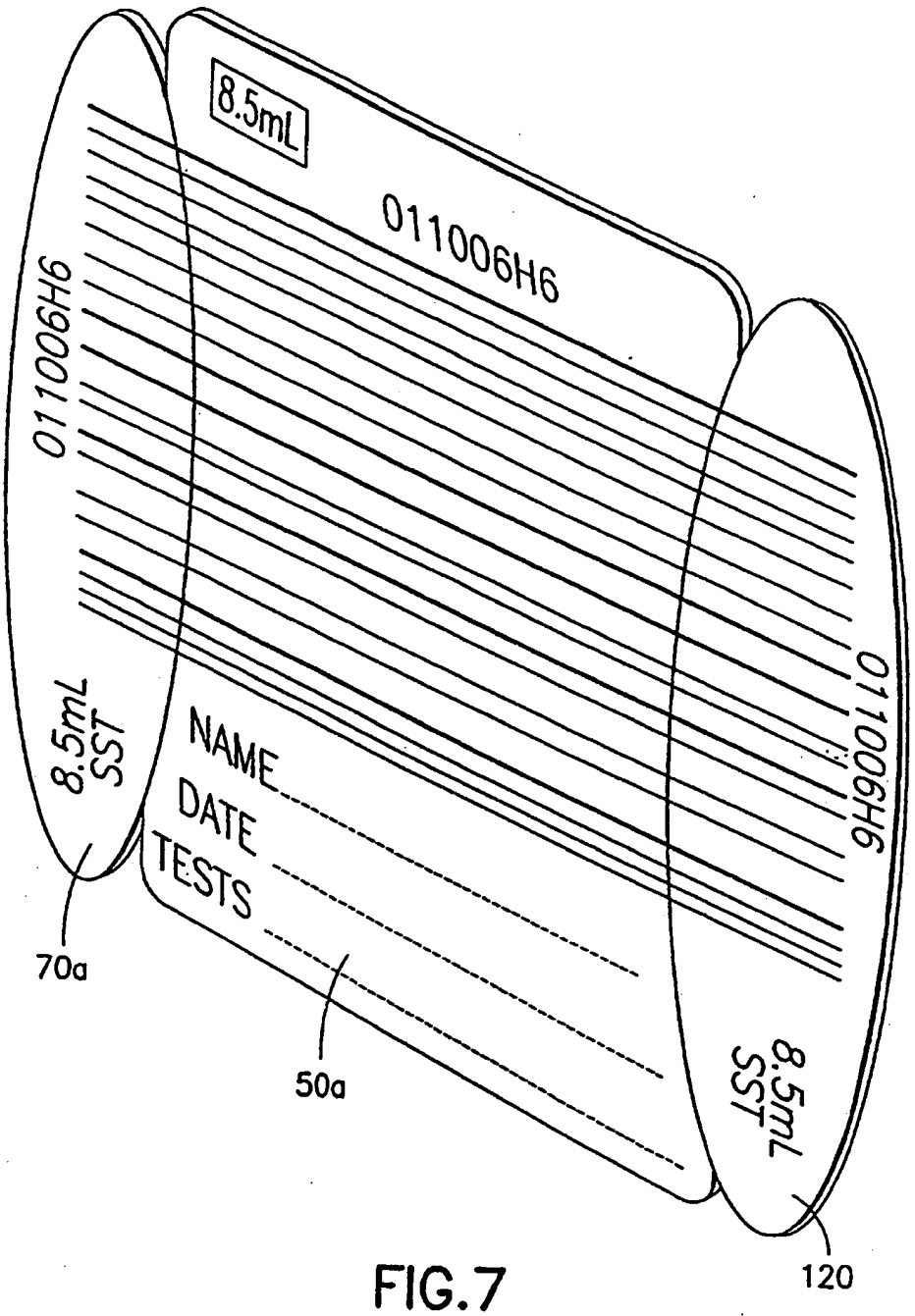
8.5mL
011006H6
011006H6
8.5mL SST
NAME
DATE
TESTS
70a
50a
011006H6
8.5mL SST
120

FIG.7

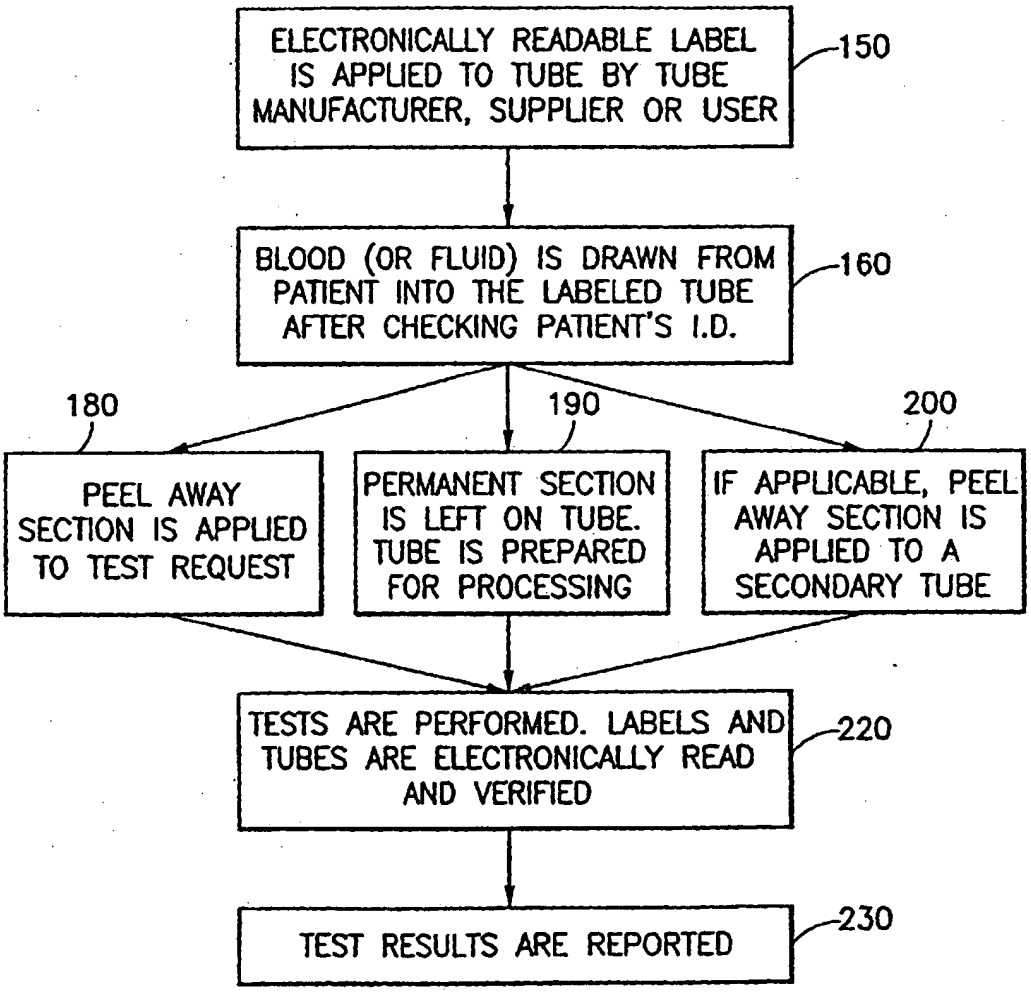
ELECTRONICALLY READABLE LABEL IS APPLIED TO TUBE BY TUBE MANUFACTURER, SUPPLIER OR USER
150
BLOOD (OR FLUID) IS DRAWN FROM PATIENT INTO THE LABELED TUBE AFTER CHECKING PATIENT'S I.D.
160
180
190
200
PEEL AWAY SECTION IS APPLIED TO TEST REQUEST
PERMANENT SECTION IS LEFT ON TUBE. TUBE IS PREPARED FOR PROCESSING
IF APPLICABLE, PEEL AWAY SECTION IS APPLIED TO A SECONDARY TUBE
TESTS ARE PERFORMED. LABELS AND TUBES ARE ELECTRONICALLY READ AND VERIFIED
220
TEST RESULTS ARE REPORTED
230

FIG.8